

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant(s): Cupp et al.
Appl. No.: 10/037,941
Conf. No.: 7917
Filed: January 3, 2002
Title: DENTAL DIET FOR REDUCING TARTAR
Art Unit: 1761
Examiner: C. Sayala
Docket No.: 115808-330

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on April 30, 2008. This Appeal is taken from the Final Rejection in the Office Action dated January 29, 2008.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Nestec, Ltd. by virtue of an Assignment dated April 11, 2002 and recorded at reel 012799, frame 0748 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 1-33 are pending in the above-identified patent application. Claims 1-33 stand rejected. Therefore, Claims 1-33 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A non-final Office Action was mailed on August 13, 2007 after prosecution was reopened in response to an Appeal Brief filed by Appellants on December 4, 2006. Appellants filed a Response on October 29, 2007 in reply to the non-final Office Action and made no amendments to the claims. A final Office Action ("Office Action") was mailed on January 29, 2008, in which the Examiner maintained the obviousness rejections. A copy of the non-final Office Action and the final Office Action are attached as Exhibits A and B, respectively, in the Evidence Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 1 is directed to a dried pet food comprising a matrix comprising a protein source, a carbohydrate source, insoluble fiber (page 3, lines 9-14; page 5, lines 1-3) and the dried pet food having an unstriated appearance (page 8, lines 20-24) and comprising a length of at least 15 mm, a width of at least 13.5 mm, and a thickness of at least 12 mm (page 3, lines 13-14 and 18), the length being greater than the thickness (pages 10-11, Examples 1 and 2) wherein the dried pet food has a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³ (page 5, lines 5).

Independent Claim 7 is directed to a dried pet food comprising a matrix comprising a protein source, a carbohydrate source, an insoluble fiber (page 3, lines 9-14; page 5, lines 1-3) and the dried pet food having an unstriated appearance (page 8, lines 20-24) and a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³ (page 5, lines 5), wherein the dried pet food comprises a thickness of at least 12 mm (page 3, lines 13-14 and 18) and a length that is greater than the thickness (pages 10-11, Examples 1 and 2).

Independent Claim 13 is directed to a dried pet food comprising a matrix comprising a protein source, a carbohydrate source, insoluble fiber (page 3, lines 9-14; page 5, lines 1-3), a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³ (page 5, lines 5) and the dried pet food comprising a length of at least 15 mm, a width of at least 13.5 mm, and a thickness of at least 12 mm (page 3, lines 13-14 and 18), wherein the length is greater than the thickness (pages 10-11, Examples 1 and 2).

Independent Claim 18 is directed to a dried pet food comprising at least 25% by weight of a kibble having an unstriated appearance (page 8, lines 20-24) and comprising a matrix having a protein source, carbohydrate source, insoluble fiber (page 3, lines 9-14; page 5, lines 1-3), and a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³ (page 5, lines 5), wherein the dried pet food comprises a thickness of at least 12 mm (page 3, lines 13-14 and 18) and a length that is greater than the thickness (pages 10-11, Examples 1 and 2).

Independent Claim 20 is directed to a method of reducing calculus and plaque build-up on a pet's teeth comprising the steps of feeding a dried pet food to a pet; and chewing by the pet

on the dried pet food having an unstriated appearance (page 8, lines 20-24) and comprising a matrix including a protein source, a carbohydrate source, insoluble fiber (page 3, lines 9-14; page 5, lines 1-3), and having a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³ (page 5, lines 5), wherein the dried pet food comprises a thickness of at least 12 mm (page 3, lines 13-14 and 18) and a length that is greater than the thickness (pages 10-11, Examples 1 and 2).

Independent Claim 21 is directed to a pet food comprising at least two different sized kibbles including a first sized kibble and a second sized kibble wherein the first sized kibble is larger in size than the second sized kibble (page 5, lines 14-15), wherein the first sized kibble and the second sized kibble are present in a ratio of approximately 20 to about 80% to approximately 80 to about 20% (page 5, lines 15-16), and at least one kibble having an unstriated appearance (page 8, lines 20-24) and a density that ranges from about 16.8 lbs/ft³ to about 20 lb/ft³ (page 5, lines 5).

Independent Claim 25 is directed to a method for making a dry pet food comprising the steps of extruding through a non-laminar flow (page 8, lines 17-19) a protein source, carbohydrate source, and an insoluble fiber source (page 3, lines 9-14; page 5, lines 1-3) to create a dry pet food having an unstriated appearance (page 8, lines 20-24) and having a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³ (page 5, lines 5), wherein the dry pet food comprises a thickness of at least 12 mm (page 3, lines 13-14 and 18) and a length that is greater than the thickness (pages 10-11, Examples 1 and 2).

Independent Claim 28 is directed to a dried pet food comprising a protein source, a carbohydrate source, an insoluble fiber source (page 3, lines 9-14; page 5, lines 1-3) and having an inner cellular structure that is created by a non-laminar flow extrusion process (page 8, lines 17-19) wherein the dried pet food has a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³ (page 5, lines 5), wherein the dried pet food comprises a thickness of at least 12 mm (page 3, lines 13-14 and 18) and a length that is greater than the thickness (pages 10-11, Examples 1 and 2).

Independent Claim 31 is directed to a dried pet food comprising a protein source, a carbohydrate source, an insoluble fiber source (page 3, lines 9-14; page 5, lines 1-3) and having an inner cellular structure that is characterized by a number of microscopic air pockets (page 8, lines 24-25) wherein the dried pet food has a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³ (page 5, lines 5), wherein the dried pet food comprises a thickness of at least 12 mm

(page 3, lines 13-14 and 18) and a length that is greater than the thickness (pages 10-11, Examples 1 and 2).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1-20 and 25-33 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,431,927 to Hand et al. ("*Hand*") and EP 0645095 to Collings et al. ("*Collings*") in view of U.S. Patent No. 6,025,004 to Speck et al. ("*Speck*") and U.S. Patent No. 4,259,361 to Procter ("*Procter*"). Copies of *Hand*, *Collings*, *Speck* and *Procter* are attached herewith as Exhibits C, D, E and F, respectively, in the Evidence Appendix.
2. Claims 21-24 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Hand* and *Collings* in view of *Speck* and *Procter* and further in view of U.S. Patent No. 5,000,490 to Staples et al. ("*Staples*") or U.S. Patent No. 5,407,661 to Simone et al. ("*Simone*"). Copies of *Staples* and *Simone* are attached herewith as Exhibits G and H, respectively, in the Evidence Appendix.

VII. ARGUMENT

A. LEGAL STANDARDS

Obviousness under 35 U.S.C. § 103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the *prima facie* case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome “by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings.” *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). “If the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.” *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference or references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Fine*, 837 F.2d 1071, 5, U.S.P.Q.2d 1596 (Fed. Cir. 1988). Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Finally, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q., 580 (CCPA 1974).

Further, the Federal Circuit has held that it is “impermissible to use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the

claimed invention is rendered obvious.” *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). “One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Moreover, the Federal Circuit has held that “obvious to try” is not the proper standard under 35 U.S.C. §103. *Ex parte Goldgaber*, 41 U.S.P.Q.2d 1172, 1177 (Fed. Cir. 1996). “An-obvious-to-try situation exists when a general disclosure may pique the scientist curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued.” *In re Eli Lilly and Co.*, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

B. THE CLAIMED INVENTION

Independent Claims 1 and 21 recite, in part, an unstriated dried pet food having density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³. This unstriated product (versus striated) of the present invention, which stems from turbulent rather than laminar flow extrusion, results in a dried pet food having a cellular structure that includes microscopic air pockets. See, specification, page 8, lines 17-24. Because of the microscopic air pockets of this unstriated dried pet food, the inner surface will have a fine, sandpaper-like appearance and a dense, foam-like structure that is in contrast to a laminar-like structure. See, specification, page 8, lines 25-30. This cellular structure improves the tartar reducing properties of the product by applying a mechanical scraping action to the teeth. See, specification, page 8 line 30 to page 9 line 15.

Independent Claims 7, 13, 18, 20, 25, 28 and 31 recite, in part, a dried pet food having a thickness of at least 12 mm, a length being greater than the thickness wherein the dried pet food has a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³.

C. THE REJECTION OF CLAIMS 1-20 AND 25-33 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS

Appellants respectfully submit that the obviousness rejection of Claims 1-20 and 25-33 should be reversed because the Examiner has failed to establish a *prima facie* case of obviousness. In the Office Action, the Examiner alleged that the combination of *Hand* in view of *Collings* in view of *Speck* and further in view of *Procter* renders the claimed subject matter obvious. However, the Examiner fails to establish a *prima facie* case of obviousness in each rejection because the cited references fail to disclose each and every limitation of the present claims. Similarly, there exists no reason that the skilled artisan would have combined the cited references to arrive at the presently claimed subject matter.

1. Even if combinable, the cited references fail to disclose or suggest each and every element of the present claims

Independent Claims 1, 7, 18, 20, 25, 28 and 31 recite, in part, a dried pet food having an unstriated appearance, a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³, and specified dimensions. In contrast, Appellants respectfully submit that the cited references fail to disclose each and every element of independent Claims 1, 13, 18, 21 and 28.

Appellants respectfully submit that, even if the cited references are combinable, the cited references, either alone or in combination, fail to disclose each and every element of the present claims. For example, because neither *Hand*, *Collings*, nor *Procter* teaches the claimed density of an unstriated pet food product, the Examiner cites to *Speck* as establishing that it was known in the art at the time the invention was made to adapt an extruder's flow characteristics in order to control the density of kibble. See, Office Action, page 6, lines 26-30. However, even assuming that *Speck* discloses modifying an extruder's flow characteristics to modify bulk density of an

extrudate, *Speck* fails to disclose or suggest any density of a pet food product, let alone the density of an unstriated dried pet food, as required, in part, by the present claims.

In the Office Action, the Examiner asserts that the density of the pet food product is obvious, in part, because the “bulk density is an important factor that is considered during manufacture because it determines the volume of the packaging or container required to market the product.” See, Office Action, page 10, lines 9-11. Appellants also submit, however, that the texture of the pet food product is also an important factor that is considered during manufacture, especially in the case of pet food products that are intended to be used to mechanically clean the teeth of pets when chewed, as is the case with the present disclosure. For example, the unstriated cellular structure of the present pet food has a dense foam-like structure that is different than previous pet foods and improves the tartar reducing properties of the product. This unstriated cellular structure is a result, in part, of the turbulent flow used in the manufacture of the pet food. See, specification, [0049-0050]. Thus, an important aspect of the presently claimed subject matter is the density of the unstriated dried pet food. As such, Appellants respectfully submit that simply because *Hand* may disclose a density of a striated pet food product between 10 and 33 lb/ft³, such a disclosure does not make the claimed density of an unstriated dried pet food obvious when combined with *Speck*, which fails to disclose or suggest any density of a pet food product, let alone the density of an unstriated dried pet food, as required, in part, by the present claims.

With respect to independent Claims 1 and 13, since neither *Hand* nor *Collings* teaches the width of the dried pet food as required, in part, by independent Claims 1 and 13, the Examiner relies on *Procter* as disclosing kibbles “of a size not greater than about ½ inch (average measurements in the three dimensions).” See, Office Action, page 7, lines 10-11 (emphasis added). The Examiner further states that because Appellants’ dried pet food has, in part, a length of 0.59 inches, a width of 0.53 inches and a thickness of 0.47 inches, that Appellants’ claims conform to the disclosure of *Procter*. See, Office Action, page 7, lines 13-18. However, Appellants respectfully disagree. For example, the disclosure of *Procter* indicates that the kibble may not be of a size greater than about ½ inch with an average measurement in three dimensions.

In contrast, the measurements of Appellants’ present claims cited by Examiner average 0.53 inches in three dimension. Clearly, Appellants’ 0.53 inch kibble is greater than *Procter*’s “about ½ inch” kibble. Moreover, in a recent opinion, the Federal Circuit stated that the term

“about” must be interpreted in its technological and stylistic context.” *Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical Labs, Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007). To properly interpret the term “about,” the Federal Circuit further stated that the use of the term in the patent specification, prosecution history, and claims should aid in determining how the inventor intended the term to be used. *Id.*

Taken in its “technological and stylistic context” in this case, the skilled artisan would recognize that *Procter* is directed toward a kibble size that is not greater than 0.50, accounting for slight variations either way. Therefore, in examining the specification and claims of *Procter*, the skilled artisan would recognize that the inventor intended the food product to include a kibble size of 0.50 inches and smaller.

Moreover, as is discussed above, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q., 580 (CCPA 1974). In contrast to the Examiner’s assertion, *Procter* fails to disclose or suggest a kibble size that is about 0.53. Therefore, because *Hand*, *Collings* and *Procter* fail to disclose a kibble size that is greater than about 0.53, the combination of the cited references cannot establish a *prima facie* case of obviousness.

Therefore, for at least the reasons discussed above, the cited references fail to teach, suggest, or even disclose each and every element of Claims 1-20 and 25-33 and thus, fail to render the present claims obvious.

2. The skilled artisan would have no reason to combine the cited references to arrive at the present claims

Appellants also respectfully submit that there exists no reason why the skilled artisan would combine the cited references to arrive at the present claims. Moreover, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. For example, Appellants respectfully submit that the previously submitted *Affidavit*, attached hereto as Exhibit I, shows that (1) the unstriated appearance and inner cellular structure resulting from a turbulent flow process significantly affects the performance of the claimed pet food as compared to other products of a striated appearance and (2) based on rheological and acoustic testing of the unstriated product of the present invention versus other striated products, these products are clearly different and present different functionalities in

terms of dental plaque and tartar reduction. As a result, the skilled artisan would not find any reason to combine a striated pet food product with an unstriated pet food product in the absence of hindsight. For example, *Collings* is directed toward an unstriated dog food product. *Hand*, by contrast, is directed toward an expanded, striated structural matrix, which teaches away from Collings and the product of the present invention.

Hand requires striations in its pet food for a specific purpose. For example, *Hand* teaches that his invention is directed to an extruded animal food product having an expanded, striated structural matrix which, when chewed by the animal, effectively removes tartar, stain and plaque on the animal's teeth through a mechanical cleansing action without causing gastrointestinal distress. When chewed, the striated product fractures along the striations whereby the animal's teeth are retained in increased abrasive contact with the fractured layers. The teeth are then mechanically cleaned by the surfaces of the separated layers as the product is chewed by the animal, and the time that the product is retained in mechanical cleaning contact with its teeth is increased. See, *Hand*, column 2, lines 26-39. As a result, the striations are an essential and functional feature of *Hand's* pet food and, thus, teach away from a combination with any unstriated pet food.

Appellants respectfully disagree with the Examiner's assertion that "*Hand et al.* teach the conditions necessary to make both the unstriated and striated pet food product, but [it] exemplifies only the striated product." See, Office Action, page 4, lines 8-10. In contrast, Appellants respectfully submit that, at best, *Hand* distinguishes turbulent flow from laminar flow and emphasizes that the product in *Hand* is created using laminar flow conditions that result in a product with an expanded striated structural matrix. As such, *Hand* teaches away from unstriated food product such as the product in *Collings*. In fact, the Examiner even admits that "[*Hand*]" does not teach that its product is unstriated." See, Office Action, page 3, line 10.

In contrast, *Collings* is entirely directed toward an unstriated dog food product having improved resistance to breakage on shipping and handling. Drop tests performed on this extruded dog treat product resulted in unacceptable breakage rates and prompted the invention in *Collings*, which is directed to a process for manufacture of a dog treat product with strong structural integrity and resistance to breaking. See, *Collings*, page 2, lines 36-44. *Collings* states that when attempting to adapt the composition and process conditions of *Hand* (SN 07/889,534 at the time of filing *Collings*) to the manufacture of a dog treat food product, it was determined

that the extruded product lacked the sufficient structural integrity to withstand the impacting internal pressure when the container holding the packaged dog treat product was dropped during handling and use. See, *Collings*, page 2, lines 30-35. Therefore, *Collings* teaches away from the composition and process of *Hand*.

With respect to the *Affidavit* previously submitted by Appellants, the Examiner states that the *Affidavit* does not establish patentability for a few reasons. One of the reasons cited by the Examiner includes the statement that since *Hand* discloses that “turbulent flow is the normal flow condition of extruded plasticized animal food products,” and since Appellants claim a pet food product produced by turbulent flow, Appellants have “not provided any reasons why patentability should be hinged on this.” See, Office Action, page 12, lines 8-12 and 29-30. However, Appellants respectfully submit that *Hand* also discloses that “fiber-containing food products which are extruded under conditions of turbulent flow contain the fibrous ingredients randomly distributed in the food product . . . when chewed by an animal, crumbles rather than fractures and exerts limited mechanical cleaning action on the animal’s teeth.” See, *Hand*, column 3, lines 35-37. In contrast to the Examiner’s statement, Appellants respectfully submit that this actually aids in demonstrating the patentability of the present claims. For example, if the “norm” for manufacturing animal food products includes turbulent flow that results in “limited mechanical cleaning action” on the teeth, and the present disclosure is directed toward the use of turbulent flow with improved mechanical cleaning on the teeth, as is demonstrated by the Examples in the specification, than *Hand* aids in demonstrating that the presently claimed subject matter is not, in fact, obvious.

The Examiner also takes issue with the alleged lack of “a nexus . . . between the merits of the claimed invention and the evidence of the [*Affidavit*].” See, Office Action, page 14, lines 1-2. Specifically, the Examiner asserts that the *Affidavit* should compare Examples 3 and 4 of the specification with *Collings* since *Collings* is directed toward an unstriated pet food product and, thus, allegedly the closest prior art. However, Appellants respectfully submit that a comparison of the presently claimed product with a “standard dry dog food” provides the proper “nexus” and a “reasonable standard for comparison” as shown in the *Affidavit*. For example, and as discussed above, the Examiner cites *Hand* as disclosing that “turbulent flow is the normal flow condition of extruded plasticized animal food products.” Similarly, Appellants respectfully submit that a “standard” dog food would most likely be produced via “normal” flow conditions. As such,

Appellants respectfully submit that a comparison between a “standard” dog food produced via turbulent flow and the presently claimed dog food produced by turbulent flow is a reasonable standard for comparison, although maybe not the only standard for comparison. However, Appellants respectfully submit that a reasonable standard for comparison should suffice so long as the comparison is relevant to the rejections. As discussed above, the comparison is relevant to the rejections by comparing two pet food products that are produced by turbulent flow. Moreover, the comparison even aids in demonstrating that the presently claimed subject matter is not, in fact, obvious, if other standard dog foods produced by turbulent flow do not produce the same cleaning action as the presently claimed pet food.

Further, Appellants respectfully disagree with the Examiner’s statement that “there are many contradictions in [Appellant’s *Affidavit*] as well as response, to make any coherent case for patentability. See, Office Action, page 14, line 13-page 15, line 13. For example, Appellants note that in the previous response dated October 29, 2007, the Remarks erroneously stated that “*Collings* is entirely directed toward a striated dog food product.” See, Response, page 4, 3d full paragraph. However, Appellants respectfully submit that the word “striated” was intended to recite “unstriated” and that recitation of the word “striated” was simply a typographical error on behalf of Appellants. The actual intent of Appellants to state that *Collings* is directed toward an unstriated product is evident in the many other places in the Response where Appellants clearly state that *Collings* is directed toward an “unstriated” dog food product. See, e.g., Response, page 4, lines 1-3; page 6, lines 5-6. Further, Appellants are not aware of any additional contradictions between the *Affidavit* and Response that would fail to “make any coherent case for patentability.” Appellants respectfully submit that one typographical error that is easily explained in view of the remaining text of the Response cannot constitute “many contradictions” that would fail “to make any coherent case for patentability.”

Moreover, Appellants respectfully disagree with the Examiner’s assertion that “*Collings* et al. is closely related to *Hand* et al. in its disclosure” because “having adapted *Hands* et al’s process (i.e., SN 07/889,534, now patent No 5431927), to obtain a product with no striations, *Collings* et al. is drawn to improving such a product’s breakage rate.” See, Non-Final Office Action, page 11, line 17-page 12, line 3. To support this assertion, the Examiner cites *Collings* as disclosing the following:

[w]hen it was attempted to adapt the composition and process conditions of SN 07/889,534 to the manufacture of a dog treat food product, that is, a product that was not in a stratified condition, it was determined that the extruded, expanded dog treat product did not have sufficient structural integrity to withstand breakage due to drop impact, i.e., the product could not satisfactorily withstand the impacting internal pressure when the container in which the dog treat product was packaged was dropped during handling and use.

See, Non-Final Office Action, page 11, lines 19-26 (citing *Collings*, page 2, lines 30-35). However, in contrast, Appellants respectfully submit that this disclosure teaches away from the use of the composition and process of *Hand* to manufacture a dog treat food product. As specifically disclosed in *Collings*, the product “did not have sufficient structural integrity to withstand breakage due to drop impact.” As such, Appellants respectfully submit that *Collings* teaches away from a combination with the composition and process of *Hand*.

Further, the process of *Collings* diverges from the initial *Hand* process by implementing wholly different post-extrusion processing steps based upon drying the extruded dog food products using, for example, different process parameters and equipment to acquire the structural integrity not accomplished using the *Hand* process. See, *Collings*, page 4, lines 1-26. Therefore, one of ordinary skill in the art should conclude that, in light of the preceding, *Collings* teaches away from the complete process in *Hand* as insufficient to meet the needs disclosed in *Collings*.

Moreover, *Collings* and *Hand* are directed to completely different objectives. While *Collings* is directed to manufacturing a dog treat product with strong structural integrity and resistance to breakage within packaging, *Hand* is directed to a pet food product that exhibits improved mechanical tooth cleansing function. Thus, while *Collings* is directed to transportation and distribution needs, *Hand* is directed to product functionality in a user’s oral cavity. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). This certainly applies here where one of the cited references is directed to a product that is intended to be striated (*Hand*) and the other cited reference is directed to a food product intended to be unstriated (*Collings*).

Procter relates to ultra homogenization of an animal protein-containing material before the application of heat to the substance. The ultra homogenization of the protein-containing

substance is used to reduce the costs of preserving, storing and transporting foods containing proteins. See, *Procter*, column 2, lines 1-8; column 1, lines 20-34. In contrast to the Examiner's assertion that *Procter* is "wholly drawn to preparing dehydrated feedstuffs for animals (column 2, lines 43-45) in the form of kibbles," Appellants respectfully submit that *Procter* is directed toward processes for preparing foodstuffs for humans, feedstuffs for animals and animal derived plant fertilizers. See, *Procter*, column 2, lines 43-46. Therefore, because *Procter* is entirely directed toward ultra homogenization of protein-containing substances to reduce cost, *Procter* is entirely unconcerned with the extrusion of a pet food product that reduces tartar.

Speck is entirely directed toward a process for mechanically controlling the bulk density of an extruded material. See, *Speck*, Abstract. The disclosure of *Speck* relates to a process in which the bulk density of an extrudate extruded through the extruder is controlled by controlling the extent which the flow restriction element restricts the flow of material through the extruder. See, *Speck*, column 2, lines 50-53. *Speck* is entirely unconcerned with the extrusion of a pet food product that reduces tartar and does not even disclose or suggest that the extrudate may be a pet food product.

In the Office Action, the Examiner asserts that "[w]ith regard to *Procter* and *Speck*, [Appellant] has discussed the objective of those inventions whereas these references were used only for their specific teachings as relevant to the instantly claimed invention." See, Office Action, page 15, lines 20-22. However, Appellants respectfully submit that the Examiner cannot simply pick and choose portions of references to use for "specific teachings as relevant to the instantly claimed invention" if the skilled artisan would have no reason to combine the reference with another reference based on the disclosures as a whole. In fact, the Federal Circuit has repeatedly held that one should not use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d at 1075. (Fed. Cir. 1988). If the Examiner were allowed to use only "specific teachings" of references that were, as a whole, completely unrelated to or having completely different objectives than the remaining references, Appellants respectfully submit that any invention could be rendered obvious.

In fact, to support the combination and/or modification of the cited art to arrive at the claimed invention, the Examiner has improperly applied hindsight reasoning by selectively piecing together teachings of each of the references in an attempt to recreate what the claimed

invention discloses. Instead, the claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983); *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). As such, Appellants respectfully submit that the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

For the reasons discussed above, Appellants respectfully submit that Claims 1-20 and 25-33 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Appellants respectfully request that the rejection of Claims 1-20 and 25-33 under 35 U.S.C. §103(a) be withdrawn.

D. THE REJECTION OF CLAIMS 21-24 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS

Appellants respectfully submit that the obviousness rejection of Claims 21-24 should be reversed because the Examiner has failed to establish a *prima facie* case of obviousness. In the Office Action, the Examiner alleged that the combination of *Hand* and *Collings* in view of *Speck* and *Procter* and further in view of *Staples* and *Simone* renders the claimed subject matter obvious. However, the Examiner fails to establish a *prima facie* case of obviousness in each rejection because, even if combinable, the cited references fail to disclose each and every limitation of the present claims.

Independent Claim 21 recites, in part, a dried pet food having a first sized kibble and second sized kibble, the first sized kibble being larger than the second, at least one kibble having an unstriated appearance and a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³. The unstriated product (versus striated) of the present invention, which stems from turbulent rather than laminar flow extrusion, results in a dried pet food having a cellular structure that includes microscopic air pockets. See, specification, page 8, lines 17-24. Because of the microscopic air pockets of this unstriated dried pet food, the inner surface will have a fine, sandpaper-like appearance and a dense, foam-like structure that is in contrast to a laminar-like structure. See, specification, page 8, lines 25-30. This cellular structure improves the tartar

reducing properties of the product by applying a mechanical scraping action to the teeth. See, specification, page 8 line 30–page 9 line 15. In contrast, Appellants respectfully submit that, even assuming that there exists a reason for the skilled artisan to combine the cited references, the cited references are deficient with respect to Claims 21-24.

For example, the cited references fail to disclose a pet food comprising at least two different sized kibbles including a first sized kibble and a second sized kibble wherein the first sized kibble is larger in size than the second sized kibble, wherein the first sized kibble and the second sized kibble are present in a ratio of approximately 20 to about 80% to approximately 80 to about 20% as required, in part, by independent Claim 21. For example, *Hand* discloses a finished product where a uniform extruded strand is cut into thick disc-shaped pellets of the same length. See, *Hand*, column 8, lines 12-17. Similarly, *Collings* discloses a uniform extruded strand cut into equally thick wavy-shaped chips. See, *Collings*, page 6, lines 1-4.

The Examiner alleges that “*Hand* shows that the extrudate was cut into 0.32 to 0.75 inch lengths to form pellets, clearly suggesting that the lengths of these kibbles were varied.” See, Office Action, page 16, lines 20-22. As support for this proposition, the Examiner cites to column 7, lines 20-22 of *Hand* which state that “the strand is cut into 0.32 to 0.75 inch lengths to form pellets and then placed in an oven at 200° F for 15 to 30 minutes.” In contrast, Appellants respectfully submit that the Examiner has misconstrued this disclosure.

For example, column 8, lines 16-17 of *Hand* illustrates a portion of an Example in which the strand “was cut into 0.50 inch thick disc-shaped pellets.” Thus, Appellants respectfully submit that the disclosure cited by the Examiner merely illustrates that the pellets may be cut into varying sizes during manufacturing, but that each of the pellets cut from that strand is cut into the same size as the others. For example, a strand may be cut to form pellets that are all 0.50 inches. Alternatively, a strand may be cut to form pellets that are all 0.6 inches. However, Appellants respectfully submit that the strands are not cut to form pellets of varying size from one strand that are present in a ratio of approximately 20 to about 80% to approximately 80 to about 20% as required, in part, by independent Claim 21.

For the reasons discussed above, Appellants respectfully submit that Claim 21 and Claims 22-24 that depend from independent Claim 21 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Appellants respectfully request that the rejection of Claims 21-24 under 35 U.S.C. §103(a) be withdrawn.

For at least the foregoing reasons, Appellants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

VIII. CONCLUSION

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 with respect to the rejections of Claims 1-33. Accordingly, Appellants respectfully submit that the obviousness rejections are erroneous in law and in fact and should therefore be reversed by this Board.

The Director is authorized to charge \$510 for the Appeal Brief and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 115808-330 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY 

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157

Dated: June 23, 2008

CLAIMS APPENDIX
PENDING CLAIMS ON APPEAL OF
U.S. PATENT APPLICATION SERIAL NO. 10/037,941

1. A dried pet food comprising a matrix comprising a protein source, a carbohydrate source, insoluble fiber and the dried pet food having an unstriated appearance and comprising a length of at least 15 mm, a width of at least 13.5 mm, and a thickness of at least 12 mm, the length being greater than the thickness wherein the dried pet food has a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³.

2. The dried pet food of Claim 1 wherein the protein source comprises denatured protein.

3. The dried pet food of Claim 1 wherein the carbohydrate source comprises gelatinized carbohydrate.

4. The dried pet food of Claim 1 wherein the insoluble fiber comprises approximately 2% to about 15% by weight of the matrix.

5. The dried pet food of Claim 1 wherein the insoluble fiber is a cellulose fiber.

6. The dried pet food of Claim 1 wherein the product does not include a humectant.

7. A dried pet food comprising a matrix comprising a protein source, a carbohydrate source, an insoluble fiber and the dried pet food having an unstriated appearance and a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³, wherein the dried pet food comprises a thickness of at least 12 mm and a length that is greater than the thickness.

8. The dried pet food of Claim 7 wherein the protein source comprises denatured protein.

9. The dried pet food of Claim 7 wherein the carbohydrate source comprises gelatinized carbohydrate.

10. The dried pet food of Claim 7 wherein the insoluble fiber comprises approximately 2% to about 15% by weight of the matrix.

11. The dried pet food of Claim 7 wherein the insoluble fiber is a cellulose fiber.

12. The dried pet food of Claim 7 wherein the product does not include a humectant.

13. A dried pet food comprising a matrix comprising a protein source, a carbohydrate source, insoluble fiber, a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³ and the dried pet food comprising a length of at least 15 mm, a width of at least 13.5 mm, and a thickness of at least 12 mm, wherein the length is greater than the thickness.

14. The dried pet food of Claim 13 wherein the protein source comprises denatured protein.

15. The dried pet food of Claim 13 wherein the carbohydrate source comprises gelatinized carbohydrate.

16. The dried pet food of Claim 13 wherein the insoluble fiber comprises approximately 2% to about 15% by weight of the matrix.

17. The dried pet food of Claim 13 wherein the product does not include a humectant.

18. A dried pet food comprising at least 25% by weight of a kibble having an unstriated appearance and comprising a matrix having a protein source, carbohydrate source, insoluble fiber, and a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³, wherein the dried pet food comprises a thickness of at least 12 mm and a length that is greater than the thickness.

19. The dried pet food of Claim 18 wherein the matrix has a length of at least 15 mm, a width of at least 13.5 mm, and a thickness of at least 12 mm.

20. A method of reducing calculus and plaque build-up on a pet's teeth comprising the steps of feeding a dried pet food to a pet; and chewing by the pet on the dried pet food having an unstriated appearance and comprising a matrix including a protein source, a carbohydrate source, insoluble fiber, and having a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³, wherein the dried pet food comprises a thickness of at least 12 mm and a length that is greater than the thickness.

21. A pet food comprising at least two different sized kibbles including a first sized kibble and a second sized kibble wherein the first sized kibble is larger in size than the second sized kibble, wherein the first sized kibble and the second sized kibble are present in a ratio of approximately 20 to about 80% to approximately 80 to about 20%, and at least one kibble having an unstriated appearance and a density that ranges from about 16.8 lbs/ft³ to about 20 lb/ft³.

22. The pet food of Claim 21 wherein at least one of the sized kibbles has a length of at least 15 mm, a width of at least 13.5 mm, and a thickness of at least 12 mm.

23. The pet food of Claim 21 wherein at least one of the sized kibbles does not include a humectant.

24. The pet food of Claim 21 wherein the ratio of large to small kibbles is 20 to 50 by number percent.

25. A method for making a dry pet food comprising the steps of extruding through a non-laminar flow a protein source, carbohydrate source, and an insoluble fiber source to create a dry pet food having an unstriated appearance and having a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³, wherein the dry pet food comprises a thickness of at least 12 mm and a length that is greater than the thickness.

26. The method of Claim 25 wherein the kibble has a length of at least 15 mm, a width of at least 13.5 mm and a thickness of at least 12 mm.

27. The method of Claim 25 wherein the insoluble fiber comprises approximately 2% to about 15% by weight of the matrix.

28. A dried pet food comprising a protein source, a carbohydrate source, an insoluble fiber source and having an inner cellular structure that is created by a non laminar flow extrusion process wherein the dried pet food has a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³, wherein the dried pet food comprises a thickness of at least 12 mm and a length that is greater than the thickness.

29. The dried pet food of Claim 28 further comprises at least one kibble that has a length of at least 15 mm, a width of at least 13.5 mm, and a thickness of at least 12 mm.

30. The dried pet food of Claim 28 further comprises at least one kibble that does not include a humectant.

31. A dried pet food comprising a protein source, a carbohydrate source, an insoluble fiber source and having an inner cellular structure that is characterized by a number of microscopic air pockets wherein the dried pet food has a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³, wherein the dried pet food comprises a thickness of at least 12 mm and a length that is greater than the thickness.

32. The dried pet food of Claim 31 wherein the interior includes circular pores.

33. The dried pet food of Claim 31 wherein the interior has a sponge-like structure.

EVIDENCE APPENDIX

EXHIBIT A: Non-Final Office Action dated August 13, 2007

EXHIBIT B: Final Office Action dated January 29, 2008

EXHIBIT C: U.S. Patent No. 5,431,927 to Hand et al ("*Hand*"), cited by the Examiner in the Office Actions dated August 13, 2007 and January 29, 2008

EXHIBIT D: EP 0645095 to Collings et al ("*Collings*"), cited by the Examiner in the Office Actions dated August 13, 2007 and January 29, 2008

EXHIBIT E U.S. Patent No. 6,025,004 to Speck et al ("*Speck*"), cited by the Examiner in the Office Actions dated August 13, 2007 and January 29, 2008

EXHIBIT F U.S. Patent No. 4,259,361 to Procter ("*Procter*"), cited by the Examiner in the Office Actions dated August 13, 2007 and January 29, 2008

EXHIBIT G U.S. Patent No. 5,000,940 to Staples et al. ("*Staples*"), cited by the Examiner in the Office Actions dated August 13, 2007 and January 29, 2008

EXHIBIT H U.S. Patent No. 5,407,661 to Simone et al. ("*Simone*"), cited by the Examiner in the Office Actions dated August 13, 2007 and January 29, 2008

EXHIBIT I: *Affidavit* under 37 C.F.R. §1.132 of Carolyn Cupp

EXHIBIT A



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/037,941

01/03/2002

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EXAMINER

SAYALA, CHHAYA D

ART UNIT

PAPER NUMBER

1761

References Downloaded

NOTIFICATION DATE

DELIVERY MODE

08/13/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding. *Due: 11-13-07: NOW Final OA*

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

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BELL, BOYD & LLOYD
INTELLECTUAL PROPERTY DOCKET

AUG 13 2007

ATTY:

DOCKET #:

hnb-mfb
115808-

00330

Office Action Summary

Application No.

10/037,941

Applicant(s)

CUPP ET AL.

Examiner

C. SAYALA

Art Unit

1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Reopening of Prosecution After Appeal

In view of the appeal brief filed on 12/5/2006, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:


KEITH HENDRICKS
PRIMARY EXAMINER

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-20, 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hand et al. (US Patent 5431927) and Collings et al. (EP 0645095) in view of Speck et al. (US Patent 6025004) and Procter (US Patent 4259361).

Hand et al. teach a pet food product made from fiber, containing protein and carbohydrate having a thickness 0.32-0.70 inch (col. 5, line 10), a length 0.32-0.75" (col. 7, lines 22-23). The width is not given and neither is the Office equipped to manufacture prior art products and compare physical dimensions or characteristics that applicant has chosen to describe his product with, with the claimed invention. Col. 8, line 17 teaches that the thickness is 0.5 inch. The product is obtained after an extrusion process and therefore it would be inherent that the protein would have been denatured and the carbohydrate gelatinized. The fiber content is given as between 10-25%. See col. 5. While the fact that little or no humectant is added to produce hard textured pet food products is well known in prior art, this patented product also does not disclose the addition of a humectant. The product is used for oral care, that reduces teeth plaque, stain and tartar. The patent teaches a product with a density between 10 to 35 lbs/cu' (see col. 4, line 44). At col. 5, lines 5-12, patentees state:

While the striated product of the present invention can be any of several shapes, the shapes which are most desirable for mechanical cleaning efficacy include a cylindrical or disc shape. Disc-shaped pellets having thickness of about 0.32 to 0.70 inch, a diameter of about 0.7 to about 1.2 inch are most preferred in the practice of the present invention. (emphasis added).

The patent does not teach that its product is unstriated. However, the patent teaches that apart from its expanded striated product obtained "by creating conditions during the extrusion of the product resembling laminar flow", and by maintaining the inner walls of the passageway at a coefficient of friction no greater than 0.2", i.e. "conditions resembling laminar flow", that produces an extrudate having striated structural matrix (col. 3, line 55 to col. 4, line 3), it is possible to produce, in contrast, fiber containing products extruded under conditions of *turbulent flow* with the fibrous ingredients randomly distributed in the food product (col. 3, lines 48-50). See col. 2, lines 44-56, that shows the contrast. See also col. 4, line 15+, that clearly delineates conditions for such a laminar flow process:

Typically, a condition resembling laminar flow is obtained in the extrudate of the present invention by passing the plasticized food ingredient mixture, heated to a temperature of about 240.degree. to about 320.degree. F. and preferably about 270.degree. to 300.degree. F. at a relatively low velocity, e.g. about 12 to about 20 in./sec., preferably about 13 to about 17 in./sec. and most preferably about 14 to about 16 in./sec., through a discharge passageway having a length of about 2 to about 4 inches and a diameter of at least about 0.35 inches and preferably about 0.5 to about 0.75 inches, the inner walls of the passageway being coated with a layer of polytetrafluoroethylene.

Therefore, by simple logic and scientific reasoning, extruding under conditions of turbulent flow, and using a coefficient of friction for the discharge passageway, which is way greater than 0.2, one of ordinary skill in the art would have reasonably expected a product that is not striated, and therefore of a different texture. Thus, Hand et al. teach the conditions necessary to make both the unstriated and striated pet food product, but exemplify only the striated product. Thus, while the ingredients are the same as claimed herein, the dimensions are comparable to those claimed, and are clearly illustrated as being of a size and shape so as to obtain the "most desirable " mechanical cleaning efficiency, the density is not the same and the product is striated.

Such an unstriated product described by Hand et al. is shown by Collings et al., wherein this reference teaches no humectant and teaches all the other limitations but not the dimensions of the product as claimed, or its density and does not subject the product with any of the conditions during extrusion as shown for the laminar product. Collings et al. disclose an extruded dog treat food product which comprises a structural matrix containing proteins, starches, carbohydrates and fiber such as cellulose (pg. 3). A typical cellulose fiber content is shown to be in the range of 2-10%. The mixture containing the starch and protein is gelatinized ("plasticized"), due to the high-temperatures of the extrusion process disclosed, and thus the end product contains denatured protein, as well as gelatinized carbohydrate. It is noted that the extrusion is done with a "heatable extruder having one or more helical transfer screws axially rotatable...., with a restricted extrusion discharge passageway" (pg. 3, lines 38-52), serving to cook and plasticize the mixture, thus providing a non-laminar flow of the

mixture through the chamber(s). Following extrusion, the pet food thus produced has a final moisture level of about 6-10% (top of page 4). Further, Collings et al. does not teach the use of a humectant. At mid-page 2, reference is made to a then copending application, 07/899,534, now US Patent 5431927 to Hand et al. (applied here), directed to a striated pet food, and at lines 30-40 of page 2, it is stated that, in contrast, Collings et al. are disclosing the production of a non-striated product, i.e. "a product that was not in a stratified condition."

When it was attempted to adapt the composition and process conditions of SN 07/889,534 to the manufacture of a dog treat food product, that is, a product that was not in a stratified condition, it was determined that the extruded, expanded dog treat product did not have sufficient structural integrity to withstand breakage due to drop impact, i.e., the product could not satisfactorily withstand the impacting internal pressure when the container in which the dog treat product was packaged was dropped during handling and use.

However, at page 4, line 1+, patentees of the EP patent, disclose the solution to this, thus:

In preparing the final dog treat food product, the final moisture content of the expanded extrudate piece, is an important feature of the present invention. To obtain an acceptable breakage resistant product, the moisture content of the final product is adjusted to the range of about 6 to about 10%. Preferably the moisture content is reduced to about 7 to about 9% by weight. At moisture levels below 6% the product becomes extremely fragile. At moisture levels above about 10%, the risk of mould growth significantly increases.

In the step of drying the extruded food products to achieve the desired final moisture level, the relationship between the drying

temperature and the length of time for the drying step, is a critical feature in the manufacture of the dog treat product of the present invention. Thus, the drying process used to obtain the final moisture level in the dog treat product requires extremely careful control of the temperature and humidity and must be done relatively slowly in order to produce a product of satisfactory breakage resistance. If the drying is carried out too quickly, i.e., at too high a temperature, e.g. above about 250°F (121°C), the dried pieces or chips of extruded product will be fragile and exhibit high breakage rates. Drying carried out too quickly, will "case harden" the extruded chips creating internal microfissures which render the product vulnerable to fragmentation along the microfissure lines.

Thus, while the patent to Hand et al. teaches the principles of obtaining the different textures, both striated and unstriated, and exemplifies one, Collings et al. exemplify the other. Furthermore, Collings et al. teach a product that resists breakage, an advantage that would be seen as beneficial by one of ordinary skill in the art, in the use of an extruded dry pet food product that has sufficient structural integrity, to be used to effectively remove tartar, stain and plaque.

Collings et al. do not teach the density of their product. Nevertheless, Speck et al. establish that it was known in the art at the time the invention was made to adapt an extruder's flow characteristics in order to control the density of kibbles, and therefore to optimize such parameters so as to obtain a density within the range shown by Hand et al. and as claimed herein, would have been within the realm of the skilled person, since Hand et al. shows that the density was for a product that had a benefit: improved oral care. With respect to claims 28-33, since Collings et al. teach non-laminar flow extrusion, then it follows that the inner cellular structure, circular pores and sponge-like

structure would result. Compare the extrusion conditions at col. 4 in '927 and pages 3-4 in '095, although the same extruders are used by both patents.

As for the dimensions of the kibble, while Hand et al. disclose the length and thickness which fall within the claimed dimensions and discloses *any suitable shape such as cylindrical or disc-shaped kibbles*, Procter teaches a kibble size not greater than "about ½ inch (average of measurements in the three dimensions)". Procter is wholly drawn to preparing dehydrated feedstuffs for animals (col 2, lines 43-45) in the form of kibbles. Therefore, applicant's claim to an extruded kibble, whose size in 3 dimensions, is that which conforms to such a prior art disclosure:

(length) 15mm= 0.59"

(width) 13.5mm= 0.53"

(thickness) 12mm= 0.47"

and is already known in prior art. Compare this with the Hand et al disclosure, a thickness of about 0.32 to 0.70 inch, a diameter of about 0.7 to about 1.2 inch as the most preferred embodiment. Furthermore, it would have been obvious to one of ordinary skill in the art who is looking to use the kibbled product for cleaning tartar, plaque and stain, that the size of a kibble should be optimized based on teeth cleaning benefits and bite size of the pet, since after all Hand et al. teach their shapes which are most desirable for mechanical cleaning efficacy, and based on this, it would not require more than ordinary skill in the art to base the size on such a need too. Since it is common knowledge that all pets do not have the same bite size, then it would have been obvious to optimize such a kibble dimension within those disclosed by the above

references, as necessary for the breed size or age (i.e. puppy, etc.) of the pet's bite size, and with the motivation to provide the tartar reducing function. Note too, that in the absence of any claim herein reciting any particular shape, if the shape were to be adapted to a bone-shape-like product (or "cylindrical" as in Hand et al.), which is the most common shape for pet food chew products, then it would follow that the length would be more than the width.

2. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hand et al. (US Patent 5431927) and Collings et al. (EP 0645095) in view of Speck et al. (US Patent 6025004) and Procter (US Patent 4259361) and further in view of Staples et al. (US Patent 5000490) or Simone et al. (US Patent 5407661).

The primary references are as described above. Claims 21-24 recite a mixture of different sized kibbles, read on having a mixture of kibbles having striated *and* non-striated appearance (note the "at least one kibble..." language), and claims 21-22 are so recited as to include a product that has a humectant. Since the prior art applied here teach both striated and unstriated appearances, both without humectant, and the size of kibbles can be optimized to about the disclosed sizes by Procter and Hand et al., and while Staples et al. or Simone et al. also disclose a product for oral care that contains a humectant, barring any evidence to the contrary, it would have been obvious to combine a variety of sizes, appearances or textures, include humectants or not, since all of the products would have reasonably been expected to provide the same function and benefit concerning the pet's oral care, since they are all drawn to the oral care of pets.

Note the ratio of a first any-sized kibble to a second any-sized kibble, 20-80%, which lends evidence to the position here, that there appears to be no criticality in either the variation of size or amount, and that a mixture such as the one claimed, provides a variety of sizes to the pet, since there is no assertion in the specification that doing so produced any patentable result. As for the variation of size, note that Hand et al. states that "the strand is cut into 0.32 to 0.75 inch and thus it would have been obvious to one of ordinary skill in the art to have provided the pet food of Collings et al. with a variety of sizes within the stated range. The same applies to other dimensions also, when prior art is considered as a whole, i.e. as applied above, because when a range of dimensions is rendered obvious from prior art, to cut an extrudate to any desired length within that range, is not inventive.

Response to Arguments

Applicant's arguments filed 12/4/2006 have been fully considered but they are not persuasive.

The arguments in the Brief are directed to Collings et al. applied under 35 USC 102(b). Since that rejection has now been withdrawn, applicant's traversal of Collings et al. will be addressed only to the extent that the traversal applies to the present rejection.

With regard to the size of the dry pet product, applicant has argued that Collings et al. shows a dimension of a moist extrudate of length 50.1 mm, width 25 mm and depth 9 mm. Further, applicant has included an extensive discussion of "thickness"

being the length, etc. Since Collings et al. have disclosed the dimensions of a moist extrudate, those dimensions are not comparable to those claimed for a dry pet food, as correctly argued by applicant, and they are not being relied upon.

On page 14 of the Brief, applicant has calculated the density of the Collings et al. product based on the dimensions of a sealed, airtight cylinder canister, disclosed at page 6 of the reference. This reasoning is unacceptable, because it is not clear if the pet food fills the entire given dimension of the package or to what extent it fills it. For further discussion please see below with reference to applicant's supplemental declaration filed 8/4/06.

Next applicant states:

Indeed, *Collings* is unconcerned with the density and size of the pet food product to provide a resultant product that can remove more plaque and tartar build-up than similar pet food products. In fact, *Collings* is directed entirely toward an expanded pet food product having improved resistance to breaking, which teaches away from the presently claimed invention. See, *Collings*, page 2, line 52 and page 5, lines 7-9.

Such a position is vigorously disagreed with. Collings et al. is closely related to Hand et al. in its disclosure. Collings et al. addresses the problem thus (see page 2, line 30+):

When it was attempted to adapt the composition and process conditions of SN 07/889,534 to the manufacture of a dog treat food product, that is, a product that was not in a stratified condition, it was determined that the extruded, expanded dog treat product did not have sufficient structural integrity to withstand breakage due to drop impact, i.e., the product could not satisfactorily withstand the impacting internal pressure when the container in which the dog treat product was packaged was dropped during handling and use. (emphasis added)

Thus, having adapted Hands et al.'s process (i.e. SN 07/889,534 now patent No 5431927), to obtain a product with no striations, Collings et al. is drawn to improving such a product's breakage rate. Thus, Hand et al. and Collings et al. disclose similar ingredients, similar extrusion apparatus, but varying conditions of extrusion that produces a striated product and an unstriated product in each case, respectively.

Also, at page 14, applicant states, with regard to the Supplemental declaration and calculations at page 14:

Nevertheless, Appellants respectfully submit that the calculations were based on reasonable assumptions regarding the overall product and packaging. For example, although the calculations did not consider the possible air space between the pet food product (which could decrease the density), the calculations balanced this by leaving out the thickness and mass of the package itself in determining the total volume and mass (which could increase the density). As a result, Appellants' previous density calculations reflected an approximate estimate of the density of the pet food product in *Collings*.

Applicant's "assumptions" and then "leaving out" certain measurements to accommodate his "assumptions", so as to arrive at a density of 12 lbs/cu ft., do not contribute to "facts" that can be relied on so as to determine, unequivocally, that these claims are patentably distinct over the applied reference(s). A close examination of the supplemental declaration and its "Density calculations" shows it is replete with "What if's", "Lets assume", "Scenario"s and "Suppose". Applicant is reminded that this is a declaration that is being weighed for facts that should provide sound reasons that distinguish the claimed invention over art of record. The supplemental declaration only

provides assumptions, scenarios, "what ifs" and hypotheses, obfuscating facts and rendering the issues even more nebulous. It is not even clear how these assumptions were made or arrived at. The declaration is self-serving and does nothing to establish patentability.

At page 15, applicant continues to maintain that Collings et al. is concerned with producing an "expanded pet food product similar to a low density puff product that tends to melt in the mouth". First, if indeed Collings et al. has an expanded pet food product, so does applicant, see instant specification at page 9, lines 15-16 that states thus. Next, the entire Collings et al. reference has been carefully reviewed and there is no disclosure of any product melting in any mouth. This is, therefore, unsubstantiated and if the Collings et al. product does so, so too should applicant's based on the fact that it too is expanded, according to the Specification.

At page 15, applicant states that since Collings fails to disclose a method of extrusion through a non-laminar flow, and then by correlating a non-laminar flow with an unstriated product, applicant concludes that Collings et al. is drawn to a *striated* product, as in Hands et al. This cannot be further than the truth for the following reasons:

First, Collings et al. as stated above, discloses:

When it was attempted to adapt the composition and process conditions of SN 07/889,534 to the manufacture of a dog treat food product, that is, a product that was not in a stratified condition, it was determined that the extruded, expanded dog treat product did not have sufficient structural integrity to withstand breakage due to drop impact, i.e., the product could not satisfactorily withstand the impacting internal pressure when the container in

which the dog treat product was packaged was dropped during handling and use. (emphasis added)

Second, none of the conditions shown in Hand et al. in order to make a striated product, is disclosed by Collings et al. for its product. To quote:

By maintaining the inner walls of the passageway at a coefficient of friction no greater than 0.2, and preferably about 0.04 to about 0.1, conditions resembling laminar flow are believed to be induced during the extrusion of the plasticized fiber containing food product of the present invention, and as a result, an extrudate having a striated structural matrix is obtained; i.e., the extrudate product has fibrous striations transversely aligned through the product microstructure.

To maintain the walls of the discharge passageway at a coefficient of friction of no greater than about 0.2, the walls are desirably coated with a coating material such as polytetrafluoroethylene which has a coefficient of friction of less than about 0.2. Polytetrafluoroethylene coating materials have a coefficient of friction in the range of about 0.04 to about 0.1 are available commercially from E.I. Dupont de Nemours under the trademarks Teflon and Silverstone. Teflon has a coefficient of friction of about 0.04. Silverstone has a coefficient of friction of about 0.1.

Typically, a condition resembling laminar flow is obtained in the extrudate of the present invention by passing the plasticized food ingredient mixture, heated to a temperature of about 240.degree. to about 320.degree. F. and preferably about 270.degree. to 300.degree. F. at a relatively low velocity, e.g. about 12 to about 20 in./sec., preferably about 13 to about 17 in./sec. and most preferably about 14 to about 16 in./sec., through a discharge passageway having a length of about 2 to about 4 inches and a diameter of at least about 0.35 inches and preferably about 0.5 to about 0.75 inches, the inner walls of the passageway being coated with a layer of polytetrafluoroethylene.
(Hand et al., col. 3, lines 63+ onto col. 4).

Third, and most importantly, applicant himself acknowledges that Collings et al. is drawn to an unstriated product and that Hands et al. is to a striated product. See the Declaration filed 2/3/2006 at paragraphs 5 and 7.

Again, Collings et al. addresses the problem that even Hand et al. has disclosed with the unstriated product:

When it was attempted to adapt the composition and process conditions of SN 07/889,534 to the manufacture of a dog treat food product, that is, a product that was not in a stratified condition, it was determined that the extruded, expanded dog treat product did not have sufficient structural integrity to withstand breakage due to drop impact, i.e., the product could not satisfactorily withstand the impacting internal pressure when the container in which the dog treat product was packaged was dropped during handling and use. (emphasis added)
Collings et al. (page 2, lines 30-37)

In contrast, fiber-containing food products which are extruded under conditions of turbulent flow contain the fibrous ingredients randomly distributed in the food product. Such food product, when chewed by an animal, crumbles rather than fractures and exerts limited mechanical cleaning action on the animal's teeth.
Hands et al. (col. 3, lines 50-54)

The above disclosures therefore clearly establish that Collings et al. is drawn to improving the unstriated product so as to make it breakage resistant, and correspondingly it follows, so that when chewed by the animal it would exert mechanical cleaning action on the animal's teeth because of this improvement.

On page 16, applicant states that the Collings product does not disclose an inner cellular structure or the microscopic air pockets. However, since the product of Collings et al. is to an unstriated product, then it follows that the product has the same characteristics as claimed. It is well settled that a patent cannot be properly granted for [an invention] which would flow naturally from the teaching of the prior art. *American Infra-Red Radiant Co. v Lambert Indus., Inc.*, 360 F.2d 977, 986 [149 USPQ 722 (CCPA 1958)], (8th Cir.) (quoting *Application of Libby*, 255 F.2d 412 [118 USPQ 194 (CCPA 1958)]), *CERT. DENIED*, 385 U.S. 920 [151 USPQ 757](1966).

On page 16, applicant also points to the Figures in both patents to Hand and Collings, and states that since they are the same, then Collings et al. is drawn to a striated product. As discussed above, this is strenuously disagreed with for the same reasons as above, and further, from the disclosure of both references, it is clear that even if the apparatus is the same, it is the differing conditions used that produce the unstriated product. See the rejection above and the discussion above as well as the references to Hand et al, as discussed in this paragraph.

The remaining pages of the Brief continue to argue the same points as discussed above, and therefore, the same response applies. In addition, to the argument presented by applicant, that Collings et al. is to a striated product also, note that the declaration makes of record that the declarant acknowledges Collings et al. is drawn to an unstriated product. See Declaration filed 2/3/06 paragraphs 5 and 7.

Finally at page 20, applicant states:

The cited references fail to disclose a pet food comprising at least two different sized kibbles including a first sized kibble and a second sized kibble

wherein the first sized kibble is larger in size than the second sized kibble, wherein the first sized kibble and the second sized kibble are present in a ratio of approximately 20 to about 80% to approximately 80 to about 20% as required, in part, by independent Claim 21. For example, Hand discloses a finished product where a uniform extruded strand is cut into thick disc-shaped pellets of the same length.


Claim 21, as stated in the rejection, recites a mixture of different sized kibbles, read on having a mixture of kibbles having striated *and* non-striated appearance (note the "at least one kibble..." language), and claims 21-22 are so recited as to include a product that has a humectant.

When Hand et al. makes it sufficiently clear that a range of dimensions for the product is possible for the purpose of cleaning teeth, and when applicant claims kibble sizes that read within the range in all its sizes, then, preparing the same sizes and mixing them is not patentable. Note too that by claiming such a mixture of products, with no size mentioned in claim 21, and dimensions that read on the applied prior art in claim 22, that contain humectant as in claims 21-22, and that may be striated as well as unstriated ("at least one kibble having a striated appearance" (claim 21)), applicant cannot argue for patentability of his product over prior art products, since such claims establish no unobviousness over such products, but in fact, establish how functionally equivalent they are, by their being used together.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


C. SAYALA
Primary Examiner
Group 1700.

Notice of References Cited	Application/Control No. 10/037,941	Applicant(s)/Patent Under Reexamination CUPP ET AL.	
	Examiner C. SAYALA	Art Unit 1761	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,025,004	02-2000	Speck et al.	426/516
*	B	US-4,259,361	03-1981	Procier, Donald	426/285
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
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	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes

Application/Control No.

10/037,941

Examiner

C. SAYALA

Applicant(s)/Patent under
Reexamination

CUPP ET AL.

Art Unit

1761

SEARCHED

Class	Subclass	Date	Examiner
426	2	8/1/2007	CS
	656		
	658		
	623		
	635		
	805		

INTERFERENCE SEARCHED

Class	Subclass	Date	Examiner

**SEARCH NOTES
(INCLUDING SEARCH STRATEGY)**

	DATE	EXMR
search transcripts appended for files USPAT, USPGPUBS, USOCR, EPO, JPO, DERWENT	8/1/2007	CS

Index of Claims



Application/Control No.

10/037,941

Examiner

C. SAYALA

Applicant(s)/Patent under
Reexamination

CUPP ET AL.

Art Unit

1761

✓	Rejected
II	Allowed

-	(Through numeral) Cancelled
+	Restricted

N	Non-Elected
I	Interference

A	Appeal
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EXHIBIT B



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/037,941

01/03/2002

Carolyn Jean Cupp

112701-330

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01/29/2008

BELL, BOYD & LLOYD LLP

P.O. Box 1135

CHICAGO, IL 60690

References Downloaded

EXAMINER

SAYALA, CHHAYA D

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

01/29/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

RECEIVED
BELL, BOYD & LLOYD
INTELLECTUAL PROPERTY DOCKET

JAN 29 2008

ATTY: *hnb-fal*DOCKET #: *115808-*

330

Office Action Summary

Application No.

10/037,941

Applicant(s)

CUPP ET AL.

Examiner

C. SAYALA

Art Unit

1794

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-20, 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hand et al. (US Patent 5431927) and Collings et al. (EP 0645095) in view of Speck et al. (US Patent 6025004) and Procter (US Patent 4259361).

Hand et al. teach a pet food product made from fiber, containing protein and carbohydrate having a thickness 0.32-0.70 inch (col. 5, line 10), a length 0.32-0.75" (col. 7, lines 22-23). The width is not given and neither is the Office equipped to manufacture prior art products and compare physical dimensions or characteristics that applicant has chosen to describe his product with, with the claimed invention. Col. 8, line 17 teaches that the thickness is 0.5 inch. The product is obtained after an extrusion process and therefore it would be inherent that the protein would have been denatured and the carbohydrate gelatinized. The fiber content is given as between 10-25%. See col. 5. While the fact that little or no humectant is added to produce hard textured pet food products is well known in prior art, this patented product also does not disclose the addition of a humectant. The product is used for oral care, that reduces teeth plaque,

stain and tartar. The patent teaches a product with a density between 10 to 35 lbs/cu' (see col. 4, line 44). At col. 5, lines 5-12, patentees state:

While the striated product of the present invention can be *any of several shapes*, the shapes which are most desirable for mechanical cleaning efficacy include a *cylindrical or disc shape*. Disc-shaped pellets having thickness of about 0.32 to 0.70 inch, a diameter of about 0.7 to about 1.2 inch are *most preferred* in the practice of the present invention. (emphasis added).

The patent does not teach that its product is unstriated. However, the patent teaches that apart from its expanded striated product obtained "by creating conditions during the extrusion of the product resembling laminar flow", and by maintaining the inner walls of the passageway at a coefficient of friction no greater than 0.2", i.e. "conditions resembling laminar flow", that produces an extrudate having striated structural matrix (col. 3, line 55 to col. 4, line 3), it is possible to produce, in contrast, fiber containing products extruded under conditions of *turbulent flow* with the fibrous ingredients randomly distributed in the food product (col. 3, lines 48-50). See col. 2, lines 44-56, that shows the contrast. See also col. 4, line 15+, that clearly delineates conditions for such a laminar flow process:

Typically, a condition resembling laminar flow is obtained in the extrudate of the present invention by passing the plasticized food ingredient mixture, heated to a temperature of about 240.degree. to about 320.degree. F. and preferably about 270.degree. to 300.degree. F. at a relatively low velocity, e.g. about 12 to about 20 in./sec., preferably about 13 to about 17 in./sec. and most preferably about 14 to

about 16 in./sec., through a discharge passageway having a length of about 2 to about 4 inches and a diameter of at least about 0.35 inches and preferably about 0.5 to about 0.75 inches, the inner walls of the passageway being coated with a layer of polytetrafluoroethylene.

Therefore, by simple logic and scientific reasoning, extruding under conditions of turbulent flow, and using a coefficient of friction for the discharge passageway, which is way greater than 0.2, one of ordinary skill in the art would have reasonably expected a product that is not striated, and therefore of a different texture. Thus, Hand et al. teach the conditions necessary to make both the unstriated and striated pet food product, but exemplify only the striated product. Therefore, while the ingredients are the same as claimed herein, the dimensions are comparable to those claimed, and are clearly illustrated as being of a size and shape so as to obtain the "most desirable" mechanical cleaning efficiency, the density is not the same and the product is striated.

Such an unstriated product described by Hand et al. is shown by Collings et al., wherein this reference teaches no humectant and teaches all the other limitations but not the dimensions of the product as claimed, or its density and does not subject the product with any of the conditions during extrusion as shown for the laminar product. Collings et al. disclose an extruded dog treat food product which comprises a structural matrix containing proteins, starches, carbohydrates and fiber such as cellulose (pg. 3). A typical cellulose fiber content is shown to be in the range of 2-10%. The mixture containing the starch and protein is gelatinized ("plasticized"), due to the high-temperatures of the extrusion process disclosed, and thus the end product contains

denatured protein, as well as gelatinized carbohydrate. It is noted that the extrusion is done with a "heatable extruder having one or more helical transfer screws axially rotatable...., with a restricted extrusion discharge passageway" (pg. 3, lines 38-52), serving to cook and plasticize the mixture, thus providing a non-laminar flow of the mixture through the chamber(s). Following extrusion, the pet food thus produced has a final moisture level of about 6-10% (top of page 4). Further, Collings et al. does not teach the use of a humectant. At mid-page 2, reference is made to a then copending application, 07/899,534, now US Patent 5431927 to Hand et al. (applied here), directed to a striated pet food, and at lines 30-40 of page 2, it is stated that, in contrast, Collings et al. are disclosing the production of a non-striated product, i.e. "a product that was not in a stratified condition."

When it was attempted to adapt the composition and process conditions of SN 07/889,534 to the manufacture of a dog treat food product, that is, a product that was not in a stratified condition, it was determined that the extruded, expanded dog treat product did not have sufficient structural integrity to withstand breakage due to drop impact, i.e., the product could not satisfactorily withstand the impacting internal pressure when the container in which the dog treat product was packaged was dropped during handling and use.

However, at page 4, line 1+, patentees of the EP patent, disclose the solution to this, thus:

In preparing the final dog treat food product, the final moisture content of the expanded extrudate piece, is an important feature of the present invention. To obtain an acceptable breakage resistant product, the moisture content of the final product is adjusted to the range of about 6 to about 10%. Preferably the

moisture content is reduced to about 7 to about 9% by weight. At moisture levels below 6% the product becomes extremely fragile. At moisture levels above about 10%, the risk of mould growth significantly increases.

In the step of drying the extruded food products to achieve the desired final moisture level, the relationship between the drying temperature and the length of time for the drying step, is a critical feature in the manufacture of the dog treat product of the present invention. Thus, the drying process used to obtain the final moisture level in the dog treat product requires extremely careful control of the temperature and humidity and must be done relatively slowly in order to produce a product of satisfactory breakage resistance. If the drying is carried out too quickly, i.e., at too high a temperature, e.g. above about 250°F (121°C), the dried pieces or chips of extruded product will be fragile and exhibit high breakage rates. Drying carried out too quickly, will "case harden" the extruded chips creating internal microfissures which render the product vulnerable to fragmentation along the microfissure lines.

As can be seen from this discussion, while the patent to Hand et al. teaches the principles of obtaining the different textures, both striated and unstriated, and exemplifies one, Collings et al. exemplify the other. Furthermore, Collings et al. teach a product that resists breakage, an advantage that would be seen as beneficial by one of ordinary skill in the art, in the use of an extruded dry pet food product that has sufficient structural integrity, to be used to effectively remove tartar, stain and plaque.

Collings et al. do not teach the density of their product. Nevertheless, Speck et al. establish that it was known in the art at the time the invention was made to adapt an extruder's flow characteristics in order to control the density of kibbles, and therefore to optimize such parameters so as to obtain a density within the range shown by Hand et al. and as claimed herein, would have been within the realm of the skilled person, since

Hand et al. shows that the density was for a product that had a benefit: improved oral care. Speck et al. also disclose that the bulk density can be controlled as well, the extruder be adjusted to yield automatically a predetermined bulk density. See col. 12, and col. 4, lines 50-55. With respect to claims 28-33, since Collings et al. teach non-laminar flow extrusion, then it follows that the inner cellular structure, circular pores and sponge-like structure would result. Compare the extrusion conditions at col. 4 in '927 and pages 3-4 in '095, although the same extruders are used by both patents.

As for the dimensions of the kibble, while Hand et al. disclose the length and thickness which fall within the claimed dimensions and discloses *any suitable shape such as cylindrical or disc-shaped kibbles*, Procter teaches a kibble size not greater than "about ½ inch (average of measurements in the three dimensions)". Procter is wholly drawn to preparing dehydrated feedstuffs for animals (col 2, lines 43-45) in the form of kibbles. Therefore, applicant's claim to an extruded kibble, whose size in 3 dimensions, is that which conforms to such a prior art disclosure:

(length) 15mm= 0.59"

(width) 13.5mm= 0.53"

(thickness) 12mm= 0.47"

and is already known in prior art. Compare this with the Hand et al disclosure, a thickness of about 0.32 to 0.70 inch, a diameter of about 0.7 to about 1.2 inch as the most preferred embodiment. Furthermore, it would have been obvious to one of ordinary skill in the art who is looking to use the kibbled product for cleaning tartar, plaque and stain, that the size of a kibble should be optimized based on teeth cleaning

benefits and bite size of the pet, since after all Hand et al. teach their shapes which are most desirable for mechanical cleaning efficacy, and based on this, it would not require more than ordinary skill in the art to base the size on such a need too. Since it is common knowledge that all pets do not have the same bite size, then it would have been obvious to optimize such a kibble dimension within those disclosed by the above references, as necessary for the breed size or age (i.e. puppy, etc.) of the pet's bite size, and with the motivation to provide the tartar reducing function. Note too, that in the absence of any claim herein reciting any particular shape, if the shape were to be adapted to a bone-shape-like product (or "cylindrical" as in Hand et al.), which is the most common shape for pet food chew products, then it would follow that the length would be more than the width. Since the method of making the pet food is rendered obvious and the pet food is for feeding a pet, then the method of claim 20 is also rendered obvious, since the discovery of a result that would flow naturally from teachings of prior art are not patentable. *In re Libby*, 118 USPQ 94 (CCPA 1958).

2. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hand et al. (US Patent 5431927) and Collings et al. (EP 0645095) in view of Speck et al. (US Patent 6025004) and Procter (US Patent 4259361) and further in view of Staples et al. (US Patent 5000490) or Simone et al. (US Patent 5407661).

The primary references are as described above. Claims 21-24 recite a mixture of different sized kibbles, read on having a mixture of kibbles having striated *and* non-striated appearance (note the "at least one kibble..." language), and claims 21-22 are

so recited as to include a product that has a humectant. Since the prior art applied here teach both striated and unstriated appearances, both without humectant, and the size of kibbles can be optimized to about the disclosed sizes by Procter and Hand et al., and while Staples et al. or Simone et al. also disclose a product for oral care that contains a humectant, barring any evidence to the contrary, it would have been obvious to combine a variety of sizes, appearances or textures, include humectants or not, since all of the products would have reasonably been expected to provide the same function and benefit concerning the pet's oral care, since they are all drawn to the oral care of pets. Note the ratio of a first any-sized kibble to a second any-sized kibble, 20-80%, which lends evidence to the position here, that there appears to be no criticality in either the variation of size or amount, and that a mixture such as the one claimed, provides a variety of sizes to the pet, since there is no assertion in the specification that doing so produced any patentable result. As for the variation of size, note that Hand et al. states that "the strand is cut into 0.32 to 0.75 inch lengths to form pellets" and thus it would have been obvious to one of ordinary skill in the art to have provided the pet food of Collings et al. with a variety of sizes within the stated range as recommended by Hand et al.. The same applies to other dimensions also, when prior art is considered as a whole, i.e. as applied above, because when a range of dimensions is rendered obvious from prior art, to cut an extrudate to any desired length within that range, is not inventive.

Response to Arguments

Applicant's arguments filed 10/29/2007 have been fully considered but they are not persuasive.

At page 2 of his Remarks, applicant has argued that Speck fails to disclose or support any density of a pet food as well as stating that neither Hand nor Proctor nor Collings teaches the claimed density of an unstriated pet food product. In response, there is no requirement in a 35 USC 103 rejection that a single reference show all the limitations claimed herein in claims 1-33. For instance, Hand discloses a pet food product with a density between 10 to about 33 lb/ft³ (col. 6, line 1). Hand et al. is to a pet food product also. Typically, pet foods are sold by weight, however, bulk density is an important factor that is considered during manufacture because it determines the volume of the packaging or container required to market the product (i.e. density multiplied by volume is mass). Typically also, pet food products are generally optimized within a largely used range by market products. For instance, applicant claims 16.8 to 20 lbs/cu. ft, and Hand discloses 10 to 33 lb/cu. ft, while Speck et al. teaches how to extrude kibbles in such a way as to not only control the bulk density of a kibbled product but to maintain the bulk density at a predetermined bulk density during extrusion. Based on such, to optimize the density within Hand's disclosed range, given Speck et al.'s disclosure, cannot be said to be inventive, and applicant has failed to show why this is so in view of prior art disclosures.

Next, applicant argues that Procter indicates that the kibble may not be greater than *about* ½ inch, an average of measurements in the three dimensions, which applicant claims does not suggest 0.53 inches, applicant's average of the

measurements claimed at claim 1. Applicant goes on to present an extensive discussion Proctor's use of "about" and urges that the skilled artisan would interpret this as $\frac{1}{2}$ inch and not "about" $\frac{1}{2}$ inch. Even if applicant's argument is considered and "about" is simply ignored, and taking into consideration Hand et al.'s disclosure of thickness and diameter for patentee's kibble (see the rejection itself), and further, taking into consideration a well known fact that kibble dimension is primarily based on bite size of the pet (which is reflected by the fact that pet food products are sold by pet size), and the fact that this rejection is under 35 USC 103, it is not clear how applicant's dimension of a kibble, which is 0.53" on an average, is so different from and unobvious compared to 0.5", also on an average, that this difference of 0.03" renders this invention patentable. The manufacture of a predetermined, particularly-sized kibble within the measurements given by Hand and even Proctor's about $\frac{1}{2}$ ", is well within the skill of the artisan, given the fact that 1) Speck et al. provides evidence that an extruder can have the extruder knife so positioned so as to cut the extrudate to a desired size kibble (col. 4, lines 48-55) and 2) the size of a kibble is based on the size of a dog/the bite size of the dog.

Next applicant has implied that the examiner has combined the references arbitrarily, that the Affidavit of record has not been considered by the examiner, and that the affidavit established that the unstriated appearance and inner cellular structure significantly affected the performance of the pet food compared to products with a striated appearance, and that the unstriated and striated products were shown to be different in functionality in terms of plaque and tartar reduction.

First, the Office action has been set out *in detail*, and applicant's statement that there is no reason why the skilled artisan would combine the cited references to arrive at the "present claims" is strenuously disagreed with in view of the reasons given for making the combination of references. Second, the affidavit has been carefully considered and does not establish patentability for the following reasons:

As stated by applicant the affidavit re-states what Hand et al. teach at col. 3 that laminar flow in extrusion, produces a striated structure, whereas applicant has used turbulent flow in the instant case and has produced an unstriated appearance. Hands et al. in this regard states the following:

Laminar flow is distinguished from turbulent flow which is the normal flow condition of extruded plasticized animal food products. In turbulent flow, fluid elements are in chaotic motion, and small random fluctuations in the velocity at a point will exist even though the average mean velocity may remain constant along its axis. Laminar flow is a flow with constant preparation of streamlines so that constant velocity surfaces remain at constant separation and laminae or sheets of fluid slide frictionless over one another. By creating conditions during the extrusion of the product resembling laminar flow, the fiber bearing ingredients in the product of the present invention are aligned in transverse striations in the product matrix. In contrast, fiber-containing food products which are extruded under conditions of turbulent flow contain the fibrous ingredients randomly distributed in the food product. Such food product, when chewed by an animal, crumbles rather than fractures and exerts limited mechanical cleaning action on the animal's teeth.

(Note col. 3, lines 35-37, in particular) ☺

If turbulent flow is the norm, applicant has not provided any reasons why patentability should be hinged on this.

The next point applicant has raised about the affidavit is that based on rheological and acoustic testing of the unstriated product of the present invention versus other striated products, these clearly products are clearly different and present different functionalities in terms of plaque and tartar reduction. In this regard the affidavit points to Examples 3 and 4 of the specification. The closest reference is that of Collings. Note applicant's statement in the affidavit at paragraph 7 with regard to Collings: "While Collings is directed toward an unstriated dog food product, Hand, by contrast is directed toward an expanded, striated structural matrix: which, in my opinion, teaches away from Collings." The comparison should therefore be made with the closest prior art. The comparison in the examples 3 and 4 of the affidavit, however, is between Purina Dog Chow and Alpo complete and the inventive product defined by claim 1 for instance. There is no explanation why these products were chosen, were they of the same size as claimed, were they striated or unstriated, etc. Applicant's comparison between the claimed product and "standard dry dog food" fails to establish a reasonable standard for comparison: On the other hand, if indeed, as Hand points out, the preparation of the standard dry dog food was prepared by the turbulent flow method, which "is the normal flow condition of extruded plasticized animal food products" and applicant's instant invention was also produced by turbulent flow (see paragraph 5 of the affidavit "Formation of the claimed dried pet food does not occur through a laminar flow extrusion process, but rather through an extrusion process that is more turbulent in nature. As a result, the dried pet food is not striated, or at least, does not have any visible striations"), then it is not clear what the comparison was based on and how this is

relevant to the rejection made. A nexus is required between the merits of the claimed invention and the evidence of secondary considerations. In order to be of any probative value the relevance of the comparison between Purina Dog Chow and Alpo complete with the claimed invention and the references that the claims have been rejected with, Should be explained by applicant. "The weight attached to evidence of secondary considerations by the examiner will depend upon its relevance to the issue of obviousness and the amount and nature of the evidence. Note the great reliance apparently placed on this type of evidence by the Supreme Court in upholding the patent in *United States v. Adams*, 383 U.S. 39, 148 USPQ 479 (1966)." Furthermore, for data presented to be relevant, it has been well established that "[A]ppellants have the burden of explaining the data in any declaration they proffer as evidence of non-obviousness." *Ex parte Ishizaka*, 24 USPQ2d 1621, 1624 (Bd. Pat. App. & Inter. 1992). Moreover, there are many contradictions in applicant's declaration as well as response, to make any coherent case for patentability.

➤ For instance at paragraph 5, applicant states as follows:

"Formation of the claimed dried pet food does not occur through a laminar flow extrusion process, but rather through an extrusion process that is more turbulent in nature. As a result, the dried pet food is not striated, or at least, does not have any visible striations"

➤ At paragraph 7, applicant states with regard to Collings:

"While Collings is directed toward an unstriated dog food product, Hand, by contrast is directed toward an expanded, striated structural matrix: which, in my opinion, teaches away from Collings."

➤ In his response filed 10/29/2007, he states at page 4, lines 1-3:

"For example, Collings is directed toward an unstriated dog food product. Hand, by contrast, is directed toward an expanded, striated structural matrix, which teaches away from Collings and the product of the present invention."

➤ In the same response, at page 4, full paragraph 3, he states:

"In contrast, Collings is entirely directed toward a striated dog food product having improved resistance to breakage on shipping and handling."

Therefore, applicant's position on the Collings product is completely confusing as to whether Collings is drawn to an unstriated product or a striated product. Based on this, applicant's traversal is also confusing.

At pages 6-7, applicant's traversal of each and every applied reference separately has been noted. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With regard to Procter and Speck, applicant has discussed the objective of those inventions whereas these references were used only for their specific teachings as relevant to the instantly claimed invention.

At page 6 of the response applicant's statement that the examiner has used improper hindsight has been noted. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With regard to the traversal at page 7, applicant's arguments have been carefully considered and it is being held that since claim 21 reads on only one kibble being unstriated, it is being assumed that the claim is open to the remaining being unstriated. Also, claim 21 includes humectants. Applicant's traversal, however appears to assume that the claim is to a product with an unstriated appearance only, and states that the combination including the Hand reference is improper. This is disagreed with. As for the different sized kibbles, this has already been addressed in the rejection. There is nothing of record, in the specification, affidavit or examples that suggests that having different sized kibbles produced any unobvious result. As applicant states, Hand discloses a finished product that was extruded to the same length and Hand does not show a variety of lengths. However, this is in error, because Hand shows that the extrudate was cut into 0.32 to 0.75 inch lengths to form pellets, clearly suggesting that the lengths of these kibbles were varied. See col. 7, lines 20-22:

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



C. SAYALA
Primary Examiner
Group 1700.

Index of Claims



Application/Control No.

10/037,941

Examiner

C. SAYALA

Applicant(s)/Patent under Reexamination

CUPP ET AL.

Art Unit

1794

✓	Rejected
=	Allowed

—	(Through numeral) Cancelled
÷	Restricted

N	Non-Elected
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EXHIBIT C

United States Patent [19]

US005431927A

Hand et al.

[11] Patent Number: 5,431,927

[45] Date of Patent: Jul. 11, 1995

[54] PET FOOD PRODUCT HAVING ORAL CARE PROPERTIES

[75] Inventors: Michael S. Hand, Maple Hill; John J. Hefferen; Brian Marlow, both of Lawrence; Lon D. Lewis, Topeka, all of Kans.

[73] Assignee: Colgate-Palmolive Company, Piscataway, N.J.

[21] Appl. No.: 899,534

[22] Filed: Jun. 16, 1992

[51] Int. Cl.⁶ A23K 1/00

[52] U.S. Cl. 426/2; 426/805; 426/443; 426/448; 426/623; 426/144; 424/49

[58] Field of Search 426/72, 73, 74, 2, 144, 426/443, 448, 449, 623, 805, 802; 424/49

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Primary Examiner—Robert A. Dawson

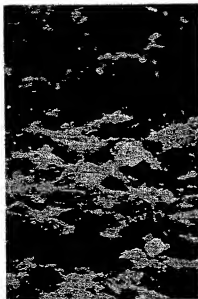
Assistant Examiner—Ana M. Fortuna
Attorney, Agent, or Firm—Paul Shapiro; Robert C. Sullivan

[57]

ABSTRACT

A pet food product prepared from a fiber containing nutritionally balanced mixture of carbohydrate protein, fat, vitamins and minerals, the product having an expanded striated structural matrix which fractures when chewed by the pet. The product when chewed by the pet exhibits an improved mechanical tooth cleansing function whereby a substantial reduction in plaque, stain and tartar on the pet's teeth is affected. The product is prepared by extruding a plasticized mixture of food ingredients through a discharge passageway, the internal walls of which are maintained at a coefficient of friction no greater than 0.2 so that a condition resembling laminar flow exists in the extrudate.

11 Claims, 2 Drawing Sheets



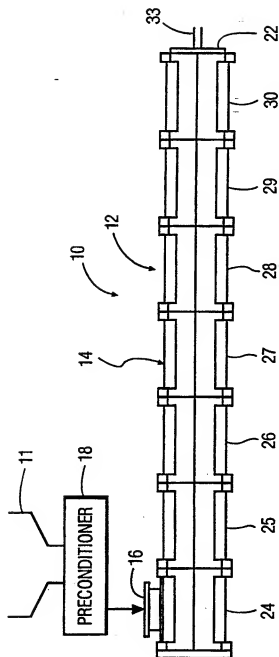


FIG. 1

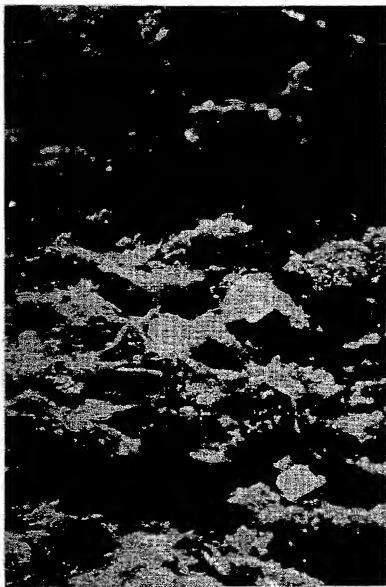


FIG. 2

PET FOOD PRODUCT HAVING ORAL CARE PROPERTIES

BACKGROUND OF THE INVENTION

1. Field of Invention

This invention relates to a solid animal food product having a structural matrix which promotes oral care and hygiene in animals. In particular this invention relates to a pet food product having an expanded, striated structural matrix which when chewed by pets such as dogs and cats, imparts an improved mechanical dental cleansing benefit to the pet's teeth.

2. Description of the Prior Art

Animal pets, such as dogs and cats, like their human counterparts, are subject to dental health problems. These problems can be traced to the formation of bacterial plaque which forms on the exterior surface of teeth. Plaque is a water white gelatinous mass of sticky film of bacteria, polysaccharides and salivary proteins which is not easily washed away. Plaque is now generally recognized as the main culprit of poor oral health. Bacteria that produce the acid for the caries process are held to the tooth surface by the plaque matrix as well as other bacterial agents which cause redness and swelling (gingivitis). The presence of these bacteria, if left untreated, may spread to cause malodor, periodontal disease, gingival pockets and bone loss.

Dental calculus, or tartar, is the result of the thickening and hardening (mineralization) of dental plaque. Tartar which is not easily removed accumulates on the tooth surface, mainly at the gingival margin. It is a hard mineral deposit containing predominantly calcium and phosphate, very tightly bound to the tooth surface. Once it is formed, tartar is extremely difficult to remove except by a veterinary professional. Tartar can become unsightly if growth is left unimpeded, and elimination is desirable as the porous surface of the calculus will be covered by a thin layer of unmineralized plaque which can cause constant irritation of the gums and can trigger other problems once calculus is formed below the gum line.

Commercial animal pet foods, when chewed by the animal, do not provide sufficient mechanical surface cleaning to teeth to provide for plaque removal from the animal's teeth necessary for optimum dental health.

A variety of products are manufactured to provide animal pets with objects to chew or gnaw. They are intended to provide the pet with exercise for the teeth to maintain a healthy condition satisfying a need which arose when the natural pet food, raw meat, was replaced with processed pet foods. Rawhide strips knotted on the ends to resemble bones, for example, provide abrasion for cleaning teeth by removing tartar and massaging the gums, which is not provided by the typical canine dog food. The rawhide dog chews are expensive, and the indigestible leather fragments swallowed by the dogs frequently cause severe gastrointestinal blockage or diarrhea.

European patent 272,968 discloses a chewable product for dogs and other domestic animals wherein certain aqueous solutions of oral care agents, e.g., sodium fluoride (anti-caries agent), sodium benzoate (anticalculus agent) and bromochlorophene (antimicrobial/antiplaque agent) are used to soak rawhide, beef tendon, or ligament. The solution treated product is then dried

whereby the oral care agents are absorbed into the surface of the product.

U.S. Pat. No. 5,011,679 discloses a tartar preventing dog chew composed of raw hide having an edible coating containing an anti-tartar alkali metal inorganic phosphate.

U.S. Pat. Nos. 5,000,940 and 5,000,943 disclose baked dog biscuits containing an inorganic pyrophosphate salt, e.g., tetrasodium pyrophosphate salt, which when chewed and/or eaten by dogs cause a reduction in tartar accumulations on their teeth.

A disadvantage of the prior art baked pet oral care products is that they are hard and brittle products and, although abrasive and initially effective to remove plaque from teeth, quickly lose their effectiveness when chewed by the animal because rapid crumbling of the product during chewing leads to loss of abrasive contact of the product with the teeth.

There is therefore a need in the pet food field for a nutritional food product which is consumable without gastrointestinal complications and effective to abrasively remove plaque when chewed by pet animals such as dogs and cats.

SUMMARY OF THE INVENTION

This invention is directed to an extruded animal food product having an expanded, striated structural matrix which, when chewed by the animal, effectively removes tartar, stain and plaque on the animal's teeth through a mechanical cleansing action without causing gastrointestinal distress. When chewed, the striated product fractures along the striations whereby the animal's teeth are retained in increased abrasive contact with the fractured layers, the teeth being abraded and mechanically cleaned by the surfaces of the separated layers as the product is chewed by the animal increasing the time that the product is retained in mechanical cleaning contact with its teeth. The extruded striated product has a low moisture content and is preferably formed from an ingredient mixture of carbohydrate, fat, protein and fiber bearing ingredients and nutritional balancing ingredients such as vitamins and minerals.

During the extrusion process to prepare the food product of the present invention, the ingredient mixture is formed into an expanded, striated product by moving the mixture under plasticizing mechanical agitation and increasing levels of temperature and shear to form a flowable mass which is advanced through a discharge passageway, the inner walls of which have a coefficient of friction no greater than 0.2, to effect a flow state through the passageway resembling laminar flow, whereby the plasticized product is extruded as a continuous strand of product in an expanded and stratified condition with the fibers incorporated in the product flowing in transverse striations.

The strand of striated product is then segmented into discrete particles or pellets by cutting means upon exit of the strand from the extruder. The pellets are then conveyed to a drying system, e.g. heated air, and the moisture level reduced to about 11% or less.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of an embodiment of an extrusion apparatus which can be used to manufacture the animal food product of the present invention.

FIG. 2 is a photomicrograph (360X magnification) of a cross-section through the food product of the present

invention having fibrous striations transversely aligned through the matrix.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

To manufacture the striated food product of the present invention, one can advantageously use a heatable extruder having one or more transfer screws within a closed heatable barrel and a restricted extrusion discharge passageway such as a die, nozzle or pipe at the front end of the barrel, the internal walls of the passageway being maintained to have a coefficient of friction no greater than about 0.2. The barrel, in conjunction with the screw and die, creates during operation a closed chamber which prevents the release of existing water vapor from the food product and system. The food product mixture of carbohydrate, protein, fat and fiber bearing ingredients is first preconditioned and moisturized with steam and water and then subjected to a plasticizing combination of temperature, shear and pressure in the extruder barrel whereby the ingredient mixture is converted into a flowable mass. The advancing mass builds up sufficient shear to cause the plasticized mixture to be pushed at the desired temperature and pressure to and through the discharge passageway.

The plasticized mixture entering the discharge passageway from the transfer screw is subjected to compression and temperature sufficiently high so that the mixture is cooked as it flows through the discharge passageway. During the passage of the plasticized mixture through the discharge passageway, due to the low coefficient of friction of the internal walls, conditions of extrudate flow are induced which are believed to approximate laminar flow.

Laminar flow is distinguished from turbulent flow which is the normal flow condition of extruded plasticized animal food products. In turbulent flow, fluid elements are in chaotic motion, and small random fluctuations in the velocity at a point will exist even though the average mean velocity may remain constant along its axis. Laminar flow is a flow with constant preparation of streamlines so that constant velocity surfaces remain at constant separation and laminae or sheets of fluid slide frictionless over one another. By creating conditions during the extrusion of the product resembling laminar flow, the fiber bearing ingredients in the product of the present invention are aligned in transverse striations in the product matrix. In contrast, fiber-containing food products which are extruded under conditions of turbulent flow contain the fibrous ingredients randomly distributed in the food product. Such food product, when chewed by an animal, crumbles rather than fractures and exerts limited mechanical cleaning action on the animal's teeth.

During extrusion of the food product of the present invention, moisture in the extrudate is in a superheated state and flashes to steam when the extrudate leaving the discharge passageway has the compression suddenly relieved, the escaping steam swells and expands the extrudate, which exits the discharge passageway in the form of a thick strand ready to be segmented into pellets or the like.

By maintaining the inner walls of the passageway at a coefficient of friction no greater than 0.2, and preferably about 0.04 to about 0.1, conditions resembling laminar flow are believed to be induced during the extrusion of the plasticized fiber containing food product of the present invention, and as a result, an extrudate having a

striated structural matrix is obtained; i.e., the extrudate product has fibrous striations transversely aligned through the product microstructure.

To maintain the walls of the discharge passageway at a coefficient of friction of no greater than about 0.2, the walls are desirably coated with a coating material such as polytetrafluoroethylene which has a coefficient of friction of less than about 0.2. Polytetrafluoroethylene coating materials have a coefficient of friction in the range of about 0.04 to about 0.1 are available commercially from E.I. DuPont de Nemours under the trademarks Teflon and Silverstone. Teflon has a coefficient of friction of about 0.04. Silverstone has a coefficient of friction of about 0.1.

Typically, a condition resembling laminar flow is obtained in the extrudate of the present invention by passing the plasticized food ingredient mixture, heated to a temperature of about 240° to about 320° F. and preferably about 270° to 300° F. at a relatively low velocity, e.g. about 12 to about 20 in./sec., preferably about 13 to about 17 in./sec. and most preferably about 14 to about 16 in./sec., through a discharge passageway having a length of about 2 to about 4 inches and a diameter of at least about 0.35 inches and preferably about 0.5 to about 0.75 inches, the inner walls of the passageway being coated with a layer of polytetrafluoroethylene.

The extruded food product of the present invention is a solid, uniform, expanded composition having fibrous striations extending transversely through the matrix microstructure. The food product, when chewed by the animal, unlike baked or other extruded products, does not crumble, but instead fractures along the matrix striations and hence offers the animal the intended teeth cleansing benefits stemming from the mechanical cleansing and other abrasive contacts with the separated matrix layers in the chewed striated product. In addition, as the striated fibrous product does not crumble as the animal chews on the product, the product clings in adhered contact with the teeth for an extended time prolonging the mechanical dental cleansing action.

The expanded, striated product of the present invention has a density of about 10 to about 35 lbs./ft³, and a typical nutritional content as follows:

Ingredient	% by Weight
Carbohydrate	about 35 to about 70
Protein	about 10 to about 35
Fat	about 10 to about 20
Fiber	about 10 to about 25
Nutritional balancing agents such as vitamins and minerals	about 0.01 to about 0.40

In preparing the final product, the moisture content of the expanded extrudate is adjusted to the range of about 5 to about 11%. At moisture levels below 5% the product becomes too hard to be easily chewed by the animal and for this reason moisture levels less than 5% in the product are to be avoided. At moisture levels above about 11% the hardness of the product begins to decrease to levels at which the mechanical cleaning efficacy of the striated product begins to be compromised. Maximum mechanical cleaning efficacy of the striated product is achieved at a density preferably of about 20 to about 30 pounds (lbs.) per cubic foot (ft³) and a fiber level preferably about 15 to about 20% by weight. At these fiber levels the product has the desired

degree of striation to achieve the desired degree of self-adhesion and tooth clinging characteristics.

To further improve palatability and energy (caloric) levels, the dried, extruded striated product may be coated with about 1 to about 13% additional fat.

While the striated product of the present invention can be any of several shapes, the shapes which are most desirable for mechanical cleaning efficacy include a cylindrical or disc shape. Disc-shaped pellets having thickness of about 0.32 to 0.70 inch, a diameter of about 0.7 to about 1.2 inch are most preferred in the practice of the present invention.

Suitable ingredients which may be used to prepare the animal food product of the present invention generally contain substantial amounts of animal protein derived from poultry by-products and high protein plant sources such as soybeans as well as fiber derived from sugar beet, soy and pure cellulose and substantial amounts of carbohydrates provided by cereals and grains such as wheat and rice as well as fats (animal or vegetable) such as tallow or soy oil. Small amounts of vitamins, minerals, salts, flavorings and preservatives are also generally included in the food product of the present invention to provide nutritional balance and palatability. A typical nutrient food product of the present invention is prepared from a mixture of the following ingredients:

Ingredient	% by Weight
Corn (Ground)	10-30
Rice Flour	30-50
Cellulose Fiber	15-25
Poultry By-product Meal	10-15
White Grease	0.5-2.0
Inorganic Salts (NaCl, KCl, Ca_2SO_4)	0.01-0.2
Vitamins	0.01-0.2
Minerals	0.01-0.2
Preservative	0.01-0.2

In preparing the striated matrix animal food product present invention, the mixture of carbohydrates, vegetable and animal protein, fat, fiber and sufficient vitamins and minerals selected to yield a nutritionally balanced diet is mixed and preconditioned or moisturized within a preconditioner or mixing cylinder wherein the ingredients are contacted with steam and moisture. The moisturized mixture is then introduced into an extruder, which can be either a single or twin screw type extruder, which cooks the mixture to yield an extruded product. The extruder is provided with at least one helical screw therethrough which axially rotates to advance the material through the extruder.

In the pre-conditioner, the mixture of ingredients is subjected to steam and moisture in order to adjust the moisture content of the mixture to between about 15 and 30% by weight. The conditioned mixture is then mixed and extruded under conditions of elevated temperature e.g. about 100° to about 250° F. and pressure, e.g., about 100 to about 1000 psi through a shaped die or nozzle, the inner walls of which are maintained at a coefficient of friction no greater than about 0.2 to form a continuous strand of an expanded striated product that is segmented into discrete pieces or pellets by rotating knives or other cutting means upon exit of the strand from the extruder. The pellets are then dried at a controlled temperature, e.g. about 200° to about 300° F. to adjust the moisture level of the extruded product to about 5 to about 11% by weight and preferably 7 to about 9% by weight. The dried pellets have a density in

the range of about 10 to about 35 lbs./ft³. Thereafter the pellets may be tumbled in a coating reel and coated with a layer of animal and vegetable oil to increase the caloric content and palatability of the product.

In FIG. 1, there is shown one embodiment of an extrusion apparatus 10 which can be used to manufacture the expanded, striated food product of the present invention. The extrusion apparatus 10 includes an extruder 12 having a barrel 14 with an inlet 16 located below the outlet of a preconditioner 18; the extruder 12 also having an outlet 20 with a die 22. Hopper 11 is provided to pre-mix the ingredients prior to preconditioning. The barrel 14 as depicted comprises seven barrel sections 24, 25, 26, 27, 28, 30, although the number of barrels may vary without departing from the principles of the present invention. The barrel sections are interconnected to present an elongated bore through the barrel 14 of the extruder 12. Two co-rotating, flighted material advancing screws (not shown) are received in the bore of the barrel and are intermeshed along the majority of the length of the extruder barrel 14 and terminate in the die section 22. The screws feed material to and through the extruder assembly, including a die 22, at an appropriate velocity and in a state of laminar flow. Extrusion apparatus 10 of the type illustrated in FIG. 1 is available from the Wenger Manufacturing Company such as the Wenger TX 80 Twin Screw Extruder. The pre-conditioner 18 shown in the Figure is also manufactured by Wenger Manufacturing, Inc.

In preparing the expanded, striated product of the present invention, the ingredients from which the food product is extruded are first mixed in a mixer such as a ribbon mixer and fed to hopper 11. These ingredients include protein materials such as poultry by-product; carbohydrates such as corn, rice; and fiber such as cellulose fiber; vitamin mix and mineral mix. The mixed ingredients are metered to the preconditioner 18 and admixed with fats such as white grease which are fed directly into the preconditioner 18 at a rate between about 0.2 to 0.4 pounds/minute (lbs./min.). In the preconditioner 18, the mixture of ingredients is fed thereto at a rate between 600 and 1200 pounds (lbs./hr.) and is further mixed with water which is introduced into the preconditioner at a rate of 60 to 140 lbs./hr (1 to 2.3 lbs./min.). The temperature of the mixture is raised from ambient to 170° to 210° F. by the injection of steam into the preconditioner 18 at the rate of 60 to 160 lbs./hr. (1 to 2.7 lbs./min.). Total residence time in the preconditioner 18 generally ranges from 0.5 to 2.5 minutes.

Preconditioning the mixture with steam and water initiates hydration of the carbohydrate and fibrous ingredients which is completed by the mechanical working during the extrusion process.

Once the mixture of ingredients and water is introduced into the extruder barrel 14, the mixture is advanced along the length of the barrel 14 by axial rotation of the screws. The mixture is sequentially advanced through the extruder and finally through the die 22 at the outlet of the extruder 12, the inner walls of the die 22 being coated with a material having a coefficient of friction no greater than 0.2. The die 22 generally consists of an elongated tubular nozzle about 2.0 to about 4.0 inches long, having an inner diameter of about 0.5 to about 1.5 inch. The inner surfaces of the die 22 are preferably coated with a polymeric coating such as a fluorinated polyolefin resin such as polytetrafluoroeth-

ylene having a coefficient of friction of about 0.04 to about 0.1. By flowing the extrudate through the coated die at a velocity of about 12 to about 20 in./sec., a condition resembling laminar flow is created in the extrudate. As the food ingredient mixture passes through the barrel sections 24, 25, 26, 27, 28, 29, and 30, it is mixed, cooked and subjected to barrel temperatures in the range of about 100° to about 250° F. preferably about 170° to about 210° F. The build-up of plasticized food ingredient mixture transferred to the die 22 by the transfer screw causes pressures of about 100 to about 1000 psi to be applied to the mixture at the die opening. The extrudate is flowed through the die 22 at a temperature of about 240° to about 320° F. Total residence time in the die 22 is about 0.10 to about 0.35 seconds.

The extrudate strand 30 as it leaves the die 22 has a moisture content of about 10 to about 40% water by weight and preferably about 15 to about 25% water by weight. The extruded strand 30 swells upon exiting the die due to flashing of moisture to steam producing an expanded, striated structure. The strand is cut into 0.32 to 0.75 inch lengths to form pellets and then placed in an oven at 200° to 240° F. for 15 to 30 minutes to dry to about 5 to about 11% moisture. At this moisture level, the dried product has a density of about 12 to about 30 lbs./ft.³.

The invention is further illustrated by the following specific but non-limiting Example.

EXAMPLE

A solid, pelletized, nutritionally balanced dog food product having an expanded, striated structural matrix was prepared in accordance with the present invention by first mixing the following ingredients:

Ingredient	Weight %
Brewers Rice	42.220
Yellow Corn	22.895
Cellulose Fiber	19.300
Poultry by-product meal	13.993
Sodium Chloride	0.362
Potassium Chloride	0.362
Calcium Sulfate	0.603
Choline Chloride	0.121
Vitamin Mix	0.048
Mineral Mix	0.048
Ethoxyquin (Preservative)	0.048

The ingredients were blended in a ribbon mixer for five minutes and milled through a hammermill having screen size of 3/64 inch.

The milled mixture was fed to the hopper 11, of a Wenger twin screw extruder (Model No. TX-80) equipped with a preconditioner 18. The TX-80 extruder was of the type schematically illustrated in the Figure and was provided with two rotatable, flighted material advancing screws and had a total of 7 barrel sections and terminated in a spacer plate die converging to a 0.75 inch diameter die, 2.87 inches in length, the inner contact surfaces of which were coated with a layer of Teflon.

The mixture, having a moisture content of 10.40%, was fed to the preconditioner at a rate of 890.0 pounds per hour. The mixture was raised in temperature to 180° F. by the injection of steam introduced at a rate of 2.17 pounds per minute into the preconditioner. Water was introduced into the preconditioner at the rate of 2.13

pounds per minute. Choice white grease was added to the preconditioner at the rate of 0.3 pounds per minute. The preconditioned mixture was fed into the inlet 16 of the extruder feeding zone. The screws of the extruder were rotated at a speed of 395 rpm.

Temperatures of the extruder barrel sections were maintained at 111° F., 154° F., 198° F., 168° F., and 183° F. and 162° F. for the second, third, fourth, fifth, sixth and seventh, barrel sections respectively. The mixture was advanced through the die at a temperature of 270° F. at a velocity of 17.9 in./sec.

Product rate through the die was 980 pounds per hour. The die issued the extrudate in the form of a strand 0.75 inch in diameter. The strand product swelled upon issuing from the die due to moisture in the extrudate flashing to steam. The strand was cut into 0.50 inch thick disc-shaped pellets. The pellets had an expanded structural matrix having fibrous striations transversely aligned through the microstructure with a water content of 23.6% by weight. The pellets were then conveyed to a forced air drying system and the moisture level reduced to 7.3% by weight at a temperature of 220° F. The dried pellets had a density of 26 lbs./ft.³. The dried pellets after exit from the dryer and prior to cooling were contacted with a liquid mixture of animal digest, choice white grease and soy bean oil heated at 120° F. within a coating reel at the following proportions:

INGREDIENTS	%
Dry pellets	86.9
Animal digest	5.0
Choice white grease	7.1
Soy bean oil	1.0

The pellets were tumbled in the coating reel for approximately 1 minute and had a uniform coating of the mixture absorbed on the pellet surfaces. The coated product was then removed from the coating reel and cooled to +10° F. of ambient temperature.

A group of 10 pure-bred beagle dogs (ages 1 to 6 years) were individually housed and fed one time per day 90-100 pellets (250 grams) prepared in accordance with the Example which was adequate to maintain the weight of each dog for a one week test period.

Throughout, and on completion of the test, the general health of the dogs remained good. No digestive upset or metabolic change was observed.

Prior to the feeding test, each dog had been given a thorough dental prophylaxis to remove existing soft and hard deposits on the buccal surfaces of the maxilla and mandible (a total of 22 teeth per dog).

The teeth of each dog in the group was examined for plaque, stain and tartar upon the completion of the test period.

In this examination, each tooth was divided horizontally into a gingival half (next to the gumline) and an occlusal half (away from the gumline). Plaque was scored visually on the corresponding tooth surfaces after staining with 3% erythrosin solution using the following criteria: 1, plaque coverage of up to 25% of the buccal tooth surface; 2, plaque covering between 25 and 50% of the buccal tooth surface; 3, plaque covering between 50 and 75% of the buccal tooth surface and 4, plaque covering between 75 and 100% of the buccal tooth surface.

The thickness of the plaque was scored as follows: Light=1, Medium=2 and Heavy=3. Coverage and thickness scores for each individual tooth surface were then multiplied, to give a total score for that tooth surface. Gingival and occlusal scores were added for each tooth. All tooth scores were added for each animal, then divided by the number of teeth scored to give a mean plaque score for the animal. A mean group plaque score was obtained by averaging individual scores of all animals in the group.

Stain was scored visually on the corresponding tooth surfaces after drying the tooth surface with a gentle jet of air using the following criteria; each tooth was divided vertically into 3 segments, mesial, buccal and distal; the coverage and color of the stain in each segment was then graded independently, 1, stain coverage of up to 25% of the (mesial, buccal or distal) surface, 2, up to 50%; 3, up to 75% and 4, up to 100%. The stain color was scored 1, L (light), 2, M (medium) and 3, D (dark). Coverage and thickness scores for each individual tooth surface were then multiplied, to give a total score for that tooth surface. Mesial, buccal and distal segment scores were added for each tooth. All tooth scores were added for each animal, then divided by the number of teeth scored to give a mean stain score for the animal. A mean group stain score was obtained by averaging individual scores of all animals in the group.

Tartar was scored visually four area coverage on the corresponding tooth surfaces in the same manner as stain.

The plaque, stain and tartar scores for this group of dogs which were fed food product are recorded in Table I below. For purposes of comparison, the procedure of the Example was repeated with the exception that the dogs were fed dry commercial pelleted dog food available from two different manufacturers, the second commercial dog food being the leading commercial dry dog food. The commercial dog food products, when fed to the dogs, were observed to crumble rather than fracture when chewed by the dogs. The results of these comparative tests are also recorded in Table I.

TABLE I

	Mean Group Plaque Score	Mean Group Stain Score	Mean Group Tartar Score
Example	8.64	3.76	5.71
Commercial Dog Food I	12.29	6.83	7.43
Commercial Dog Food II	11.16	5.88	7.31

An examination of the scores recorded in Table I clearly show that the food product prepared in the Example, is significantly effective in reducing plaque, stain and tartar in dogs, especially when compared to the comparative commercial dry, pelleted dog food products.

The significance of the effectiveness of the dog food prepared in accordance with the practice of the present invention is demonstrated in Table II. Based on the mean group scores of Table I, the percent reduction obtained in plaque, stain and tartar obtained with the food products of the present invention (Example) as compared with the commercial comparative products are summarized in Table II below.

TABLE II

	% REDUCTION IN PLAQUE, STAIN AND TARTAR ACHIEVED WITH DOG FOOD PRODUCT OF PRESENT INVENTION WHEN COMPARED TO COMMERCIAL DOG FOOD PRODUCTS		
	% Plaque Reduction	% Stain Reduction	% Tartar Reduction
Commercial Dog Food I	29.7	44.9	23.1
Commercial Dog Food II	22.6	36.1	21.9

For purposes of further comparison, a dog food product was prepared in accordance with the procedure of the Example with the exception that the inner walls of the die used for the extrusion of the product were not coated with Teflon or any other low coefficient of friction coating; examination of the matrix of the product indicated that the fibrous ingredient was randomly distributed in the matrix.

The pelleted product, when fed to dogs, was observed to crumble rather than fracture when chewed by the dogs.

What is claimed is:

1. An animal food product comprised of a mixture containing proteins, fats, carbohydrates, fibers, vitamins and minerals the product having a matrix which, when chewed by an animal, is effective for removing plaque, tartar and stain from the teeth of the animal, the matrix being comprised of an extruded, expanded striated product having the fibers aligned in transverse striations through the matrix, the matrix being fractureable, and effective to induce a superior mechanical cleaning action on the animals teeth when chewed.

2. The food product of claim 1 wherein the product is prepared from a mixture containing about 35 to about 70% by carbohydrate, about 10 to about 35% by weight protein, about 10 to about 20% by weight fat and about 10 to about 25% by weight fiber.

3. The food product of claim 1 wherein the striated matrix has a density of about 10 to about 35 lbs/ft³ and a moisture content of about 5 to 11% by weight.

4. A method of removing plaque, tartar and stain from the teeth of an animal which comprises preparing the animal food product of claim 1, and feeding the food product to the animal.

5. The method of claim 4 wherein the product is prepared from a mixture containing about 35 to about 70% by carbohydrate, about 10 to about 35% by weight protein, about 10 to about 20% by weight fat and about 10 to about 25% by weight fiber.

6. The method of claim 4 wherein the striated matrix has a density of about 10 to about 35 lbs/ft³ and a moisture content of about 5 to 11% by weight.

7. The food product of claim 1 wherein the fiber is cellulose fiber.

8. A method of preparing an animal food product which is effective for removing plaque, tartar and stain from the teeth of an animal which comprises preparing a food mixture containing carbohydrates, proteins, fats and fiber bearing ingredients, working the mixture under mechanical pressure and heat sufficient to convert the mixture to a plasticized flowable mass and discharging the mass through a die, the internal walls of the die being maintained at a coefficient of friction of from 0.04 to 0.2 so as to obtain an expanded extrudate product having the fiber bearing ingredients aligned in transverse striations through the matrix which, when

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chewed by an animal, fractures and imparts an improved mechanical cleansing action to the animal's teeth.

9. The method of claim 7 wherein the inner walls of

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the discharge passage is coated with a fluorinated polyolefin.

10. The method of claim 9 wherein the fluorinated polyolefin is a polytetrafluoroethylene.

11. The method of claim 8 wherein the fiber bearing ingredients are cellulose fiber.

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EXHIBIT D



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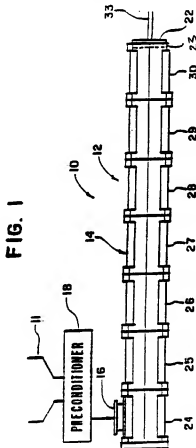
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(54) Extruded dog treat food product having improved resistance to breakage.

(57) A dog treat food product is disclosed which is extruded from a nutritionally balanced mixture of carbohydrate, protein, fat, vitamins and minerals. The dog treat food product exhibits improved resistance to breakage on impact by drying pieces of the extrudate under controlled conditions of humidity to a moisture level of between 6-10% by weight at a relative humidity of about 5 to about 25%, a dry bulb temperature of about 150 to about 250°F, a wet bulb temperature of about 105 to about 150°F and for at least 15 minutes.



BACKGROUND OF THE INVENTIONFIELD OF INVENTION

5 This invention relates to an extruded dog food product and in particular to an extruded dog food product having improved resistance to breakage on shipping and handling.

PRIOR ART

10 The nutrition and health of dogs is one of the most important aspects of pet care. Most dog owners wish to provide their dogs a well-balanced and healthy diet. As people are becoming much more aware of their own personal nutrition, there is an increased awareness in the importance of providing balanced nutrition in the form of pet food and pet treats.

Dogs should be fed a balanced diet combining water, proteins, carbohydrates, fats, minerals and vitamins. Pet owners routinely treat their dogs with a variety of snack foods made for this purpose. Many of these snack foods are not nutritionally balanced for a particular life stage. It is therefore proposed to provide a canine food product that the pet owner can give to his dog as a treat while maintaining the balance of nutrients necessary for good health.

In copending patent application US Serial No. 07/899,534 filed June 16, 1992 corresponding to EP Appli-
cation No.

20 there is disclosed an extruded animal food product having an expanded, striated structural matrix which when chewed by the animal effectively removes tartar, stain and plaque from the animal's teeth through a mechanical cleansing action. The extruded expanded food product has a low moisture content and is formed from an ingredient mixture of carbohydrate, fat, protein and fibre-bearing ingredients and nutritional balancing ingredients such as vitamins and minerals.

25 In preparing the pet food product of SN 07/899,534, the ingredient mixture is formed into pieces by moving the mixture under plasticizing mechanical agitation and increasing levels of temperature and shear to form a flowable mass which is advanced through a die of predetermined diameter having a coefficient of friction no greater than 0.2 to form a continuous strand of product in an expanded and stratified condition. The product when formed into pieces exhibits strong structural integrity and is not subject to breakage on handling.

30 When it was attempted to adapt the composition and process conditions of SN 07/899,534 to the manufacture of a dog treat food product, that is, a product that was not in a stratified condition, it was determined that the extruded, expanded dog treat product did not have sufficient structural integrity to withstand breakage due to drop impact, i.e., the product could not satisfactorily withstand the impacting internal pressure when the container in which the dog treat product was packaged was dropped during handling and use. Drop impact
35 tests performed on the dog treat product packaged in cardboard canisters i.e., the number of broken pieces as represented as a percentage of total weight, indicated an unacceptable breakage rate, i.e. greater than 10%, and as high as 60-80%.

Therefore, there is a need in the pet food field for a nutritive, extruded dog food treat product which exhibits resistance to breakage when packaged and handled.

SUMMARY OF THE INVENTION

The present invention is directed to a process for the manufacture of an extruded dog treat food product which exhibits strong structural integrity and is resistant to breakage; wherein an ingredient mixture of carbo-
45 hydrate, fat, protein, and nutritional balancing ingredients such as vitamins and minerals are extruded as a continuous strand of shaped product in an expanded condition. The strand of expanded product is segmented into discrete pieces or chips upon exit of the strand from the extruder. The pieces are then dried in moisturised heated air, and the final moisture content of the product reduced to about 6 to about 10% by weight, in an atmosphere of about 5 to 25% relative humidity, a dry bulb temperature of about 150 to about 250°F (66°C to 121°C), and a wet bulb temperature of about 105 to about 150°F (41°C to 66°C), the pieces being exposed to these drying conditions for at least 15 minutes.

50 The extruded food product of the present invention is a solid, uniform, expanded composition. When tested for breakage in drop impact tests, the % breakage is in the range of about 4-6%. In a preferred embodiment of the invention, fibre-bearing ingredients are included in the ingredient mixture from which the expanded dog treat food product is prepared. Extruded dog treat food products containing about 2 to about 10% by weight
55 of fibre-bearing ingredients exhibit drop impact breakage levels of less than 3%.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The extruded expanded product of the present invention has a typical nutritional content as follows:

Ingredient	% by Weight
Carbohydrate	about 20 to about 70
Protein	about 12 to about 30
Fat	about 3 to about 20
Nutritional balancing agents (vitamins and minerals)	about 0.5 to about 5

Suitable ingredients which may be used to prepare the extruded food product of the present invention generally contain substantial amounts of animal protein derived from protein sources such as poultry by-products and whole dried eggs; fibre derived from beet pulp, soy mill run and purified cellulose; carbohydrates provided by carbohydrate sources such as cereals and grains such as wheat, corn and rice; and fats derived from fat sources such as choice white grease and vegetable oil. Small amounts of vitamins, mineral salts, flavourings, colourants and preservatives are also generally included in the food product of the present invention to provide nutritional balance and palatability. A preferred dog treat food product dried in accordance with the process of the present invention is prepared from a mixture of the following ingredients.

Ingredient	% by Weight
Corn (Ground)	40 - 70
Cellulose Fibre	2 - 10
Poultry By-Product Meal	20 - 30
White Grease	1 - 10
Inorganic Salts ((NaCl, KCl, CaCO ₃))	0.5 - 2.0
Vitamins	0.01 - 0.2
Trace Minerals	0.01 - 0.2
Preservatives	0.01 - 0.2

In preparing the extruded, expanded dog treat product of the present invention, the mixture of ingredients selected to yield a nutritionally balanced diet is mixed and preconditioned (or moisturised within a preconditioner or mixing cylinder) wherein the ingredients are contacted with steam and moisture. The moisturised mixture is then introduced into the preconditioner of a heatable extruder having one or more helical transfer screws axially rotatable within a closed heatable barrel and equipped with a restricted extrusion discharge passageway such as a die at the front end of the barrel.

In the pre-conditioner, the mixture of ingredients is subjected to steam and moisture in order to adjust the moisture content of the mixture to between about 15 and 30% by weight. The moisture conditioned mixture is then mixed and advanced through the barrel of the extruder by the axially rotating screws which plasticise the mixture. The advancing mass builds up sufficient shear to cause the plasticized mixture to form a flowable mass to be advanced at the desired temperature, e.g., 100-250°F (38°C to 121°C), and pressure e.g., 100 to 1000 psi through a shaped die mounted at the front end of the extruder barrel. The plasticising combination of temperature shear and pressure subjects the mixture to compression and temperature sufficiently high so that it is cooked or gelatinized as it advances through the extruder barrel.

As the food product of the present invention is extruded from the die, the moisture in the extrudate is in a superheated state and flashes to steam when the extrudate leaving the die has the compression suddenly relieved whereby the escaping steam swells and expands the extrudate. This extrudate exits the die in the form of a thick strand of expanded mass which is segmented into pieces or chips by rotating knives or other cutting means. The chips are then dried under carefully controlled conditions of temperature and humidity to obtain a breakage resistant product.

In preparing the final dog treat food product, the final moisture content of the expanded extrudate pieces is an important feature of the present invention. To obtain an acceptable breakage resistant product, the moisture content of the final product is adjusted to the range of about 6 to about 10%. Preferably the moisture content is reduced to about 7 to about 9% by weight. At moisture levels below 6% the product becomes extremely fragile. At moisture levels above about 10%, the risk of mould growth significantly increases.

In the step of drying the extruded food products to achieve the desired final moisture level, the relationship between the drying temperature and the length of time for the drying step, is a critical feature in the manufacture of the dog treat product of the present invention. Thus, the drying process used to obtain the final moisture level in the dog treat product requires extremely careful control of the temperature and humidity and must be done relatively slowly in order to produce a product of satisfactory breakage resistance. If the drying is carried out too quickly, i.e., at too high a temperature, e.g. above about 250°F (121°C), the dried pieces or chips of extruded product will be fragile and exhibit high breakage rates. Drying carried out too quickly, will "case harden" the extruded chips creating internal microfissures which render the product vulnerable to fragmentation along the microfissure lines.

To reduce the moisture content of the extruded chips, the chips are dried in a dryer, e.g. a hot air humidity controlled circulating oven adjusted to a relative humidity of about 5 to about 25%. Relative humidity (RH) is defined in a standard manner as the ratio of vapour pressure in the air to the saturation vapour pressure at the same temperature and is expressed as %. These conditions of relative humidity are achieved at dry bulb temperatures in the range of about 150 to about 250°F (66°C to 121°C) and wet bulb temperatures of about 105 to about 150°F (41°C to 66°C), and preferably a dry bulb temperature in the range of about 160 to about 210°F (71°C to 99°C) and a wet bulb temperature in the range of about 110 to about 130°F (43°C to 54°C).

To advantageously accomplish drying of the extruded dog treat product of the present invention at a relative humidity within the range of about 5 to about 25% and a dry bulb temperature of about 150 to 250°F and a wet bulb temperature of 105 to 150°F, the product is exposed to these drying conditions for a period of at least about 15 minutes and preferably about 20 to about 120 minutes and most preferably about 45 to about 90 minutes.

The invention may be put into practice in various ways and one specific embodiment will be described to illustrate the invention with reference to the accompanying drawing in which

FIG. 1 is a schematic presentation of an extrusion system used to manufacture the dog treat food product of the present invention.

In Figure 1, there is shown one embodiment of an extrusion apparatus 10 which can be used to manufacture the extruded, expanded food product of the present invention. The extrusion apparatus 10 includes an extruder 12 having a barrel 14 with an inlet 16 located below the outlet of a preconditioner 18; the extruder 12 also having an outlet equipped with a die section 22. Hopper 11 is provided to pre-mix the ingredients prior to preconditioning. The barrel 14, as depicted, comprises seven barrel sections 24, 25, 26, 27, 28, 29, 30, although the number of barrel section may vary without departing from the principles of the present invention. The barrel sections are interconnected to present an elongated bore through the barrel 14 of the extruder 12. Two co-rotating, flighted material advancing screws (not shown) are received in the bore of the barrel and are intermeshed along the length of the extruder barrel 14 and terminate in the die section 22. The screws feed material to and through the extruder assembly, including the die 22, at an appropriate velocity. A spacer ring 23 is inserted between the terminal end of the rotating screws (not shown) and the adjacent face of the die 22. The spacer ring 23 provides a small surge area to dampen the effects of the twin screws so that the flow of plasticised mass is more even. Extrusion apparatus 10 of the type illustrated in figure 1 is available from the Wenger Manufacturing Company such as the Wenger TX52 Twin Screw Extruder. The pre-conditioner 18 shown in Figure 1 is also manufactured by Wenger Manufacturing, Inc.

In preparing the expanded, extruded dog treat product of the present invention, the ingredients from which the dog treat is extruded are first mixed in a mixer such as a ribbon mixer and fed to hopper 11. These ingredients include protein materials such as poultry by-product meal; carbohydrates such as ground yellow corn and vitamin mix and mineral mix. In a preferred embodiment a fibre bearing ingredient such as beet pulp or cellulose fibre, is included in the ingredient mixture. The mixed ingredients are metered to the preconditioner 18 and admixed with fats such as white grease which are fed directly in the preconditioner 18 at a rate between about 0.4 to 0.6 pounds/minute (lbs./min) (0.18 to 0.27 kgs/min). In the preconditioner 18, the mixture of ingredients is fed thereto at a rate between 4 and 10 lbs./min (1.8 to 4.5 kgs/min). The temperature of the mixture is raised from ambient to 120 to 212°F (49 to 100°C) by the injection of steam into the preconditioner 18 at the rate of 0.2 to 0.6 lbs./min (0.09 to 0.27 kgs/min). Total residence time in the preconditioner 18 generally ranges from 2 to 15 minutes.

Preconditioning the mixture with steam and water initiates hydration of the carbohydrate and fibrous ingredients which is completed by the mechanical working during the extrusion process. Once the mixture of

ingredients and water is introduced into the extruder barrel 14, the mixture is advanced along the length of the barrel 14 by axial rotation of the screws. The mixture is sequentially advanced through the extruder and finally through the die 22. As the dog treat ingredient mixture passes through the barrel sections 24, 25, 26, 27, 28, 29 and 30, it is mixed and cooked. The build-up of the plasticised food ingredient mixture transferred to the die 22 by the rotating transfer screws causes pressures of about 50 to about 300 psi to be applied to the mixture at the die opening.

The extrudate strand 33 as it leaves the die 22 has a moisture content of about 15 to about 25% water by weight and preferably about 18 to about 20% water by weight. The extruded strand 33 swells upon exiting the die due to flashing of moisture to steam producing an expanded structure. The strand is cut into 46 to 55 mm lengths of pieces or chips and then placed in an oven and subjected to drying under controlled conditions of humidity e.g., about 5 to about 25% relative humidity at about 150 to about 250°F (dry bulb) and about 105 to about 150°F (wet bulb) for at least 15 minutes and generally about 20 to 120 minutes to reduce the moisture level of the chips to about 6 to about 10% moisture.

The invention is further illustrated by the following specific but non-limiting Examples.

EXAMPLES 1A, B and C

A solid nutritionally balanced dog treat food product designated Composition A (Example 1A) having an expanded structural matrix was prepared in accordance with the present invention by first mixing the following ingredients:

<u>Ingredient</u>	<u>Weight%</u>
Ground Yellow Corn	57.385
Poultry By-Product Meal	26.315
Cellulose Fibre ¹	5.000
Choice White Grease	5.700
Sodium Chloride	0.333
Dicalcium Phosphate	1.710
Potassium Chloride	0.40
Choline Chloride	0.095
Vitamin Mix	0.105
Mineral Mix	0.033
Iron Oxide	0.029
Ethoxyquin (Preservative)	0.019
¹ cellulose fibres of 60 microns average length.	

The ingredients (except the choice white grease) were milled through a hammer mill having screen size of 3/64 inch (0.1 cm) and then blended in a ribbon mixer for 2-3 minutes.

The blended mixture was fed to the hopper 11, of a Wenger twin screw extruder (Model No. TX 52) equipped with a preconditioner 18. The Wenger TX 52 extruder was of the type schematically illustrated in Figure 1 and was provided with two rotatable, flighted material advancing screws and had a total of 7 barrel sections and terminated in a spacer plate die.

The mixture, having a moisture content of 14.5%, was fed to the preconditioner at a rate of 6.5 lbs/min (2.95 kgs/min). The mixture was raised in temperature to 190°F (88°C) by the injection of steam introduced at a rate of 0.6 lbs/min (0.27 kgs/min) into the preconditioner. Water was introduced into the preconditioner at the rate of 0.7 lbs/min (0.32 kgs/min). Choice white grease was added to the preconditioner at the rate of 0.4 lbs/min (0.18 kgs/min). The preconditioned mixture was fed into the inlet 16 of the extruder feeding zone. The screws of the extruder were rotated at a speed of 450 rpm.

Temperatures of the extruder barrel sections were maintained at 180°F (82°C), 190°F (88°C), 210°F (99°C), 215°F (102°C) and 230°F (110°C) and 235°F (118°C) for the second, third, fourth, fifth, sixth and sev-

enth, barrel sections respectively. The die issued the extrudate in the form of an expanded strand 50.1 mm in length, 25 mm in width and 9 mm in depth. The strand product swelled upon issuing from the die due to moisture in the extrudate flashing to steam. The strand having a moisture content of 18% by weight was cut into 10mm thick wavy-shaped chips.

The chips were then conveyed to a forced air drying system and the moisture level reduced to 8.8% by weight under controlled conditions of humidity. The dryer was set to a dry bulb reading of 205°F (96°C) and a wet bulb reading of 125°F (52°C), whereby a relative humidity of 13% was maintained. The extruded product was placed on perforated trays and exposed to these conditions for 45 minutes whereby the final moisture level of 8.8% was achieved.

The dried product was packaged in a sealed, air tight, 5" diameter x 8" tall (12.7 x 20.3cm) cardboard cylindrical canisters which weighed 500 grams when filled.

After one week storage, the sealed canisters were subjected to a drop test to determine whether the dog treat product could satisfactorily withstand the impacting internal pressure when the canisters containing the dog treat chips were dropped during shipping or handling. In the drop test, 48 sealed canisters containing the dog treat chips were packaged in corrugated boxes (12 per box) and the boxes dropped from a height of three feet, three times in succession. Thereafter, the dog treat chip contents of the canisters were inspected for product damage and % breakage determined. Percent breakage was determined as the number of broken pieces represented as a percent of total weight of product in each canister. A percent breakage of below 10% was considered acceptable in the drop test.

The procedure of Example 1A was repeated with the exception that the 5% cellulose fibre content of Composition A was modified by substituting 5% beet pulp (Composition B) or 5% Soy Mill Run (Composition C) as the fibre-bearing ingredient. The results of the drop test are summarised in Table 1 below.

Table 1

Example	Composition	% Breakage	Std.Dev.
1A	A	0.78	1.3
1B	B	2.3	2.6
1C	C	2.9	2.7

The results recorded in Table 1 indicate that the drop impact breakage of the extruded expanded fibre reinforced dog treat product can be reduced to below 3% by drying the product to a moisture level below 10% at a RH of 13% and a dry bulb/wet bulb temperature of 205/125°F for 45 minutes. Packaged dog treat product reinforced with cellulose fibre exhibited the least breakage when dropped.

Examples 2A, B, C and D

The procedure of Example 1 was repeated to manufacture a dog treat product using the following ingredients:

Ingredient	Wt. %
Ground Yellow Corn	60.41
Brewers Rice	3.00
Poultry By-Product Meal	27.70
Sodium Chloride	0.35
Choice White Grease	6.00
Potassium Chloride	0.45
Dicalcium Phosphate	1.80
Choline Chloride	0.10
Vitamin Mix	0.11
Mineral Mix	0.035
Iron Oxide	0.03
Ethoxyquin	0.02

The dog treat food product was dried to moisture levels of 6.0-8.8% at varying R.H. and dry/wet bulb temperatures for varying time periods. The dried dog food treat was then subjected to drop tests of the type described in Example 1 to determine its resistance to breakage. The results are recorded in Table II below.

Table II

Example	Final Product Moisture (%)	Dry Bulb/ Wet Bulb Temp. (°F)	Drying			
			RH (%)	Time (Min.)	Breakage %	Std. Dev.
2A	8.7	160/112	25	78	3.8	2.6
2B	8.7	205/125	13	45	5.3	4.0
2C	6.0	285/115	1.1	1.7	25.0	6.4
2D	7.3	283/116	1.0	13	25.2	10.1

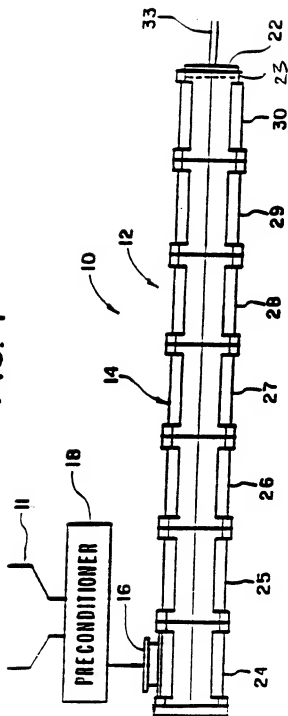
The results recorded in Table II show that the extruded expanded dog treat food product in which a fibre bearing ingredient is absent when dried in accordance with the process of the present invention (Examples 2A and 2B) exhibits an impact breakage of about 4 - 5% whereas the same product (Examples 2C and 2D) dried under temperature, time and RH conditions outside the scope of the present invention exhibited unacceptable (25%) breakage levels.

Claims

1. A dog treat food product containing carbohydrate, protein, fat and nutritional balancing agent ingredients which is an expanded extrudate product and has a moisture content of about 6 to about 10% by weight.
2. A method of preparing a dog treat food product which exhibits reduced physical breakage during shipping and handling which comprises working a food mixture containing carbohydrate, protein, fat and nutritional balancing agent ingredients, under mechanical pressure and heat sufficient to convert the mixture to a flowable mass, passing the mass through a die to obtain an expanded extrudate product, segmenting the extrudate into pieces and then drying the pieces to a final moisture content of about 6.0 to about 10.0% by weight.

3. A method as claimed in claim 2 in which the said drying is carried out in an atmosphere of about 5 to about 25% relative humidity, a dry bulb temperature of about 150 to about 250°F, and a wet bulb temperature of about 105 to about 150°F, the pieces being exposed to these drying conditions for a period of at least 15 minutes.
4. A method as claimed in claim 1 or claim 2 characterised in that a fibre bearing ingredient is incorporated in the dog treat product.
5. A method as claimed in claim 4 characterised in that the fibre bearing ingredient is cellulose fibre, beat pulp or soy mill run.
6. A method as claimed in any one of the preceding claims characterised in that the pieces are dried for about 20 to about 120 minutes.
7. A method as claimed in any one of the preceding claims characterised in that the pieces are dried to a moisture content of about 7 to about 9% by weight.
8. A method as claimed in any one of the preceding claims characterised in that the food mixture has a nutritional content of about 20 to about 70% by weight carbohydrate, about 20 to about 30% by weight protein, about 3 to about 20% by weight fat and about 0.5 to about 5% by weight nutritional balancing agents.
9. A method as claimed in any one of the preceding claims characterised in that the fibre bearing ingredient is incorporated in the food mixture at a concentration of about 2 to about 10% by weight.

FIG. 1



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 94 30 6877

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
P, X, D	EP-A-0 575 021 (COLGATE-PALMOLIVE COMPANY) * page 4, lines 29-33, page 5, lines 19-29, example, claims * ---	1,2,4-9	A23K1/18 A23K1/00
X	US-A-4 020 187 (MCCULLOCH ET AL.) * column 1, line 59 - column 2, line 19, examples * ---	1,2,4,5, 7-9	
X	DE-A-22 04 049 (RALSTON PURINA CO.) * page 3, line 3, table (page 7), examples * ---	1,2,4,5, 8,9	
X Y	CA-A-1 172 092 (GENERAL FOODS CORPORATION U.S.A.) * page 4, line 15 - page 5, line 7, page 22, lines 10 - 14 * ---	1,2,4,5, 7-9 1-9	
X Y	US-A-4 310 558 (NAHM JR.) * column 2, line 47, column 3, line 57, table III, examples * ---	1,2,4,5, 8,9 1-9	TECHNICAL FIELDS SEARCHED (Int.Cl.6) A23K
X	PATENT ABSTRACTS OF JAPAN vol. 12, no. 312 (C-523) 24 August 1988 & JP-A-63 084 451 (NIPPON PET SANGYO KK) 15 April 1988 * abstract * ---	1,2,4,5, 7	
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The present search report has been drawn up for all claims			
Place of search MUNICH		Date of completion of the search 30 December 1994	Examiner Bendl, E
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons A : number of the same patent family, corresponding document			

EP 0 645 095 A1 (P44C1)

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EUROPEAN SEARCH REPORT

Application Number
EP 94 30 6877

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	US-A-4 143 169 (SKOCH ET AL.) * column 4, line 41 * ----	1,2,4,5, 7-9	
Y	SCHORMÜLLER JOSEF 'Lehrbuch der Lebensmittelchemie' 1974, SPRINGER-VERLAG, BERLIN, HEIDELBERG, NEW YORK pages 279, 280: "Trocknung der Lebensmittel" * page 280, first full paragraph * -----	1-9	
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The present search report has been drawn up for all claims			
Place of search MUNICH		Date of completion of the search 30 December 1994	Examiner Bendl, E
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background U : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

EP 0 FORM 1800 (04/94) (EN/CA)

EXHIBIT E

United States Patent [19]

Speck et al.

[11] Patent Number: 6,025,004

[45] Date of Patent: Feb. 15, 2000

[54] PROCESS FOR MECHANICALLY CONTROLLING THE BULK DENSITY OF AN EXTRUDED FOOD MATERIAL

[75] Inventors: Donald R. Speck, Festus; Alfred H. Miruau, St. Louis, both of Mo.

[73] Assignee: Ralston Purina Company, St. Louis, Mo.

[21] Appl. No.: 08/887,037

[22] Filed: Jul. 2, 1997

[51] Int. Cl.⁷ A23P 1/00

[52] U.S. Cl. 426/516; 426/448

[58] Field of Search 426/516, 447, 426/448; 425/382.4

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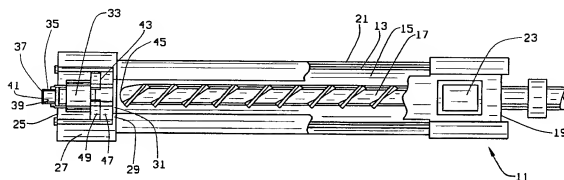
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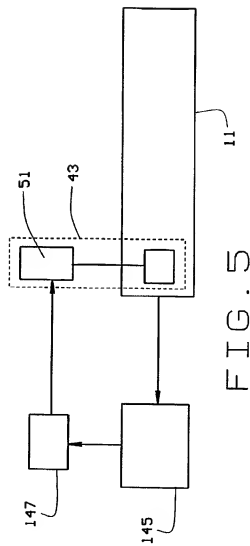
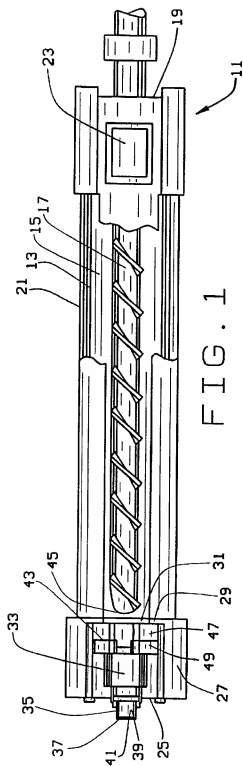
Primary Examiner—George C. Yeung
Attorney, Agent, or Firm—Herzog, Crebs & McGhee, LLP

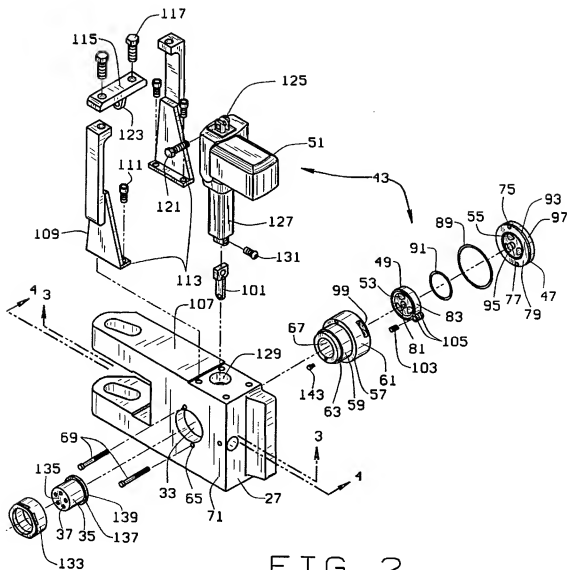
[57] ABSTRACT

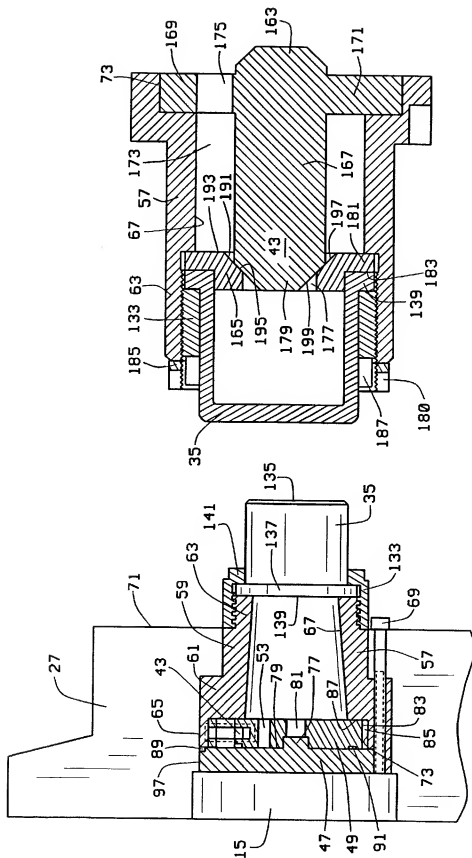
An adjustable variable flow restriction element and an extruder containing the same are provided for mechanically controlling the bulk density of an extruded material. The adjustable flow restriction element is located in an extruder proximate to the die of the extruder in position to partially block the downstream flow of material through the extruder. The adjustable flow restriction element is structured to be capable of assuming one of a plurality of uniquely flow restrictive positions, where the degree of restriction of flow controls the bulk density of an extruded material. A method of mechanically controlling the bulk density of an extruded material by restricting the flow of the material through an extruder is also provided.

11 Claims, 4 Drawing Sheets

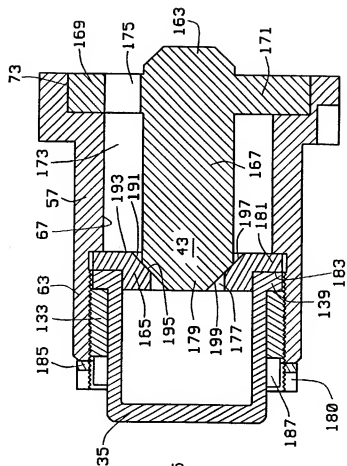








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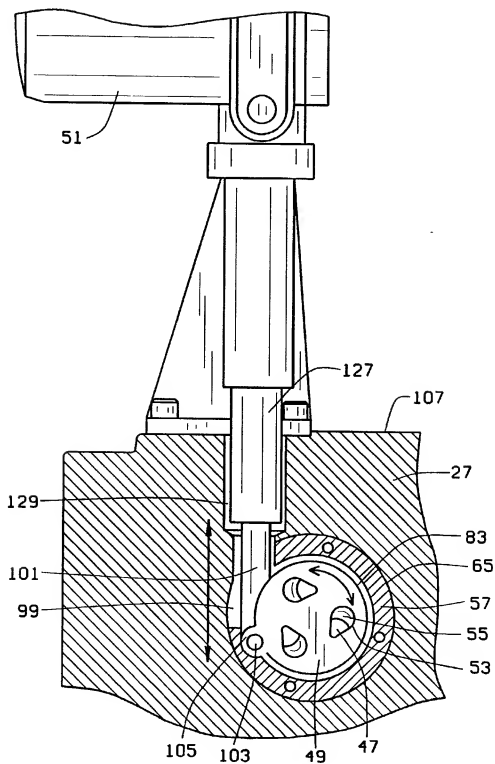


FIG. 4

PROCESS FOR MECHANICALLY CONTROLLING THE BULK DENSITY OF AN EXTRUDED FOOD MATERIAL

BACKGROUND OF THE INVENTION

The present invention provides a method and an apparatus for extruding an extrudate with a controlled bulk density. In particular, the present invention provides an extruder with a variable restriction element which can be used to control the bulk density of the extrudate as the extrudate is extruded from the extruder, and a process of controlling the bulk density of an extrudate with a variable restriction element.

Extruders are commonly used to extrude thermoplastic materials such as plastics and moisturized feedstuffs formed of farinaceous and proteinaceous materials. The extruder heats and pressurizes the thermoplastic material and forces the material through an extruder die, whereupon the extruded material is cut into a desired shape as it exits the extruder die. For example, in the formation of dry kibbled pet foods a mixture of farinaceous and proteinaceous material is mixed with water, plasticized, and cooked as it is pushed through the extruder under pressure, and is subsequently cut into kibbles as it is extruded through the extruder die.

Maintenance of an extrudate having a constant bulk density is important to maintain consistent product size and package weights in the production of extruded foods. A common method to maintain the bulk density of extruded foodstuffs at constant levels is to adjust the moisture content of the material being extruded, which varies the inherent lubricity of the extrudate. The bulk density of the extrudate may be increased by increasing the moisture content of the material being extruded since higher levels of moisture reduce the energy imparted to the extrudate by the extruder screw, reducing expansion of the extrudate. Inversely, decreasing the moisture content of the material being extruded increases the expansion of the extrudate which decreases the bulk density of the extrudate. Moisture levels in the material can be controlled by adding steam or water to the material prior to extrusion, or injecting steam or water into the material as it passes through the extruder.

Use of the moisture content of the extruded material to control the bulk density of the extrudate subsequent to extrusion introduces variability into the quality of the final food product. Typically, an extrudate is dried in a dryer after being extruded through the die and cut to the desired size. Extrudate containing different levels of moisture will dry to an extent dependent on the amount of moisture in the extrudate when the extrudate is dried for a set period of time in a dryer. Extrudates containing relatively little moisture will tend to be burnt by the drying process, and extrudates containing excessive moisture will not completely dry, leading to a food product susceptible to mold.

In large scale commercial applications several extruders are often serviced by one dryer, and the variations in moisture levels of different extrudates entering the dryer can be large, resulting in great variation in the product exiting the dryer. The ultimate quality of the product may be adversely affected by these variations. For example, a burnt pet food kibble may not be palatable to the pet for which it is intended, and a moist pet food kibble may be unacceptable because of mold spoilage.

A recently published article authored by S. Shonauer and R. Moreira entitled *A Variable Restrictive Valve as an Extra Independent Control Variable For Food Extrusion Processes* (Food Science and Technology International, Vol. 2,

pp. 241-48 (1996)) discloses the use of a restriction valve located in the die of an extruder extending across the die outlet orifice as a method of controlling the bulk density of a food extrudate without changing the moisture content of the extrudate. At relatively closed restriction valve positions the bulk density of the extrudate is low since the extrudate expands significantly as it exits the restricted die orifice under pressure from the extruder screw. At relatively open restriction valve positions the bulk density of the extrudate is high since little expansion occurs as the extrudate exits the die orifice.

The die restriction valve of Shonauer and Moreira, while permitting control of the bulk density of an extruded product, causes variations in the extruded product as the valve is positioned at various levels of restriction. Throttling the die restriction valve changes the die geometry and produces a thinner extrudate. For production of extruded foods having uniform characteristics, use of a die restriction valve is not particularly desirable since the die restriction valve causes variations in the thickness of the extrudate.

Further, Shonauer and Moreira do not suggest that a die restriction valve can be adjusted to continuously control bulk density while the extruder is in operation. In a commercial food extruding process the ability to continuously adjust the bulk density without altering the moisture level of the food in the extruder while the extruder is in operation is desirable to produce a uniform product.

SUMMARY OF THE INVENTION

The present invention is an extruder which can mechanically control the bulk density of an extrudate without altering the moisture level of the components to be extruded in the extruder, and without causing variations in the form of the extruded product. The extruder has an elongated extruder barrel which extends about and defines an extrusion chamber. An extruder die is secured at an outlet end of the extruder adjoining the extrusion chamber. The extruder die has an orifice extending therethrough through which material can be extruded which is in communication with the extrusion chamber. An adjustable flow restriction element is secured within the extruder barrel proximate to the extruder die. The adjustable flow restriction element is structured and arranged to adopt a plurality of positions restricting the downstream flow of material through the extruder, where each position of the plurality of positions is uniquely restrictive. The adjustable flow restriction element is further structured and arranged to be adjustable between each of the plurality of positions as material flows through the extruder to alter the extent which the flow restriction element restricts flow of material through the extruder. The bulk density of an extrudate extruded through the extruder is controlled by controlling the extent which the flow restriction element restricts the flow of material through the extruder.

In another aspect, the invention is a method for mechanically controlling the bulk density of an extrudate of a continuously extruded food material. A food material is continuously extruded through an extruder to form an extrudate. An overall area within the extruder through which the food material can flow and which is proximate to the extruder outlet is mechanically controlled to control the bulk density of the extrudate. In one embodiment of the invention, the bulk density of the extrudate is controlled by maintaining the bulk density at a predetermined bulk density. In another embodiment of the invention, the bulk density of the extrudate is controlled by altering the bulk density of the extrudate from a first bulk density to a second bulk density.

In still another aspect, the invention is an adjustable flow restriction element apparatus for location in an extruder proximate to the die of the extruder which is useful for mechanically controlling the bulk density level of a material continuously extruded through the extruder. The flow restriction element apparatus has a fixed component, a movable component, and means for moving the movable component relative to the fixed component. The fixed component is structured and arranged to be fixedly secured in an extruder proximate to the extruder die. The movable component is located proximate to the fixed component so the movable component and the fixed component are structured and arranged to be jointly located in the extruder across the downstream flow of material through the extruder. The movable component is movable relative to the fixed component so the movable component can adopt a plurality of positions relative to the fixed component, where each of the positions of the movable component to the fixed component is capable of uniquely restricting the downstream flow of material through the extruder in which the fixed and movable components are located.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic view of an embodiment of an extruder formed in accordance with the present invention.

FIG. 2 is an exploded view of an extruder door including an extruder die, die housing, and a preferred embodiment of an adjustable flow restriction element formed in accordance with the present invention.

FIG. 3 is a cross-sectional view of the extruder door, extruder die, die housing, and adjustable flow restriction element of FIG. 2 viewed along the lines A-A'.

FIG. 4 is a cross-sectional view of the extruder door, die housing, and adjustable flow restriction element of FIG. 2 viewed along the lines B-B'.

FIG. 5 is a schematic view of an extruder, adjustable flow restriction element, means for measuring bulk density, and means for providing feedback.

FIG. 6 is a cross-sectional view of an extruder die housing, an extruder die, and another embodiment of an adjustable flow restriction element.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIG. 1, an embodiment of an extruder 11 formed in accordance with the present invention is shown. The extruder 11 has an extruder barrel 13 which extends about and encloses an extrusion chamber 15 through which a material passes as it is extruded through the extruder. An extruder screw 17 extends lengthwise through the extrusion chamber 15 in the extruder barrel 13 from an inlet end 19 of the extruder 11 for a substantial portion of the length of the extruder barrel 13. A motor (not shown) or other conventional power generator is coupled or linked to the screw 17 proximate to the inlet end 19 of the extruder 11 to provide power to rotate the screw 17. The extruder screw 17 is structured and arranged to rotate and feed material through the extruder 11 in a conventional manner. The extruder 11 may be provided with a plurality of steam or water jackets 21 for heating and cooking material passing through the extruder 11.

An inlet 23 is located in the inlet end 19 of the extruder 11 for receiving materials, preferably food materials, for extrusion through the extruder 11. Typically, food materials are moisturized and premixed in a preconditioner (not

shown) which is coupled to the inlet 23 of the extruder 11 to deliver the preconditioned food material into the extruder 11. The inlet 23 communicates with the extrusion chamber 15 so material delivered through the inlet 23 is deposited in the extrusion chamber 15 positioned to be moved through the extruder 11 from the inlet end 19 to the outlet end 25 of the extruder 11 by the action of the screw 17.

An end cap 27 is removably coupled to an end plate 29 extending across the extrusion chamber 15 at the outlet end 25 of the extruder barrel 13. The end plate 29 has a centrally located aperture 31 extending therethrough which coincides with, and forms a part of, the extrusion chamber 15. The end cap 27 extends about and defines an end cap chamber 33 which aligns with the aperture 31 in the end plate 29 and the extrusion chamber 15, and forms part of the extrusion chamber 15 when the end cap 27 is coupled to the end plate 29.

In a preferred embodiment, the end cap 27 is an extruder door, and henceforth will be referred to as an extruder door. The extruder door 27 is structured to be securely fastened to the end plate 29 so as to form a pressure fluid seal capable of withstanding the high pressures generated within the extrusion chamber 15 during extrusion. In one embodiment, the extruder door 27 may be bolted to the end plate 29. In a preferred embodiment, the extruder door 27 is hingedly coupled to the end plate 29 and may be removably latched to the end plate 29, as described in U.S. Pat. No. 3,561,371 to Kummer, which is incorporated herein by reference.

An extruder die 35 is secured at the outlet end 25 of the extruder 11 adjoining the extrusion chamber 15. Preferably, the extruder die 35 is coupled to the extruder door 27 in communication with the extruder door chamber 33 portion of the extrusion chamber 15. The extruder die 35 may be removably coupled to the extruder door 27 so that the extruder die 35 may be interchanged with other extruder dies. In a particularly preferred embodiment, the extruder die 35 is threadably coupled to the extruder door 27 so the extruder die may be removed from or inserted in the extruder 11 by unscrewing or screwing the extruder die 35.

The extruder die 35 has at least one orifice 37 extending therethrough in communication with the extrusion chamber 15 through which material passing through the extruder 11 may be extruded. The extruder die 35 is positioned in the extruder 11 with an inlet end 39 of each orifice 37 adjoining and in communication with the extruder door chamber 33, and an outlet end 41 of each orifice 37 located at the outlet end 25 of the extruder. An extruder knife (not shown) is located spaced slightly apart from the outlet end of the orifices 37 positioned to cut material extruded through the die orifices 37 into desirable lengths of extrudate as the material exits the die 35. In a particularly preferred embodiment, the extruder knife is positioned to cut extruded food material into kibbles as the extrudate exits the die, where the kibbles may be used as a pet food material.

In a preferred embodiment, the extruder die 35 may be selected from a plurality of dies having different orifice configurations and characteristics. The cross-sectional shape, diameter, and number of orifices 37 in the die 35 are important in determining the shape of the extrudate extruded from the die and the rate at which material can be extruded from the extruder. The extruder die 35 having the desired orifice 37 characteristics to best produce the desired extruded product may be selected from the plurality of dies.

An adjustable flow restriction element 43 is located in the extruder 11 in the extrusion chamber 15 between the tip 45 of the screw 17 and the extruder die 35 for mechanically

controlling the bulk density of material extruded from the extruder. In a preferred embodiment, the adjustable flow restriction element 43 is secured in the extruder door 27 located in the extruder door chamber 33 portion of the extrusion chamber 15 in a position to be adjusted to partially block the downstream flow of material through the extrusion chamber 15.

The adjustable flow restriction element 43 can control the bulk density of a material extruded from the extruder 11 by adjustably restricting the flow of the material in the extruder near the extruder die 35, and thereby controlling the degree of expansion and bulk density of the material extruded through the die 35. The adjustable flow restriction element 43 is structured and arranged in the extruder to adopt a plurality of positions which can restrict the downstream flow of material through the extruder 11 from the screw 17 to the die 35. Each position of the plurality of positions can uniquely restrict the downstream flow of material through the extruder 11 by uniquely determining the overall area through which the extruded material may flow through the flow restriction element 43. The adjustable flow restriction element 43 is further structured and arranged in the extruder 11 to be adjustable between each position of the plurality of uniquely restrictive positions as material flows through the extruder so the flow restriction element 43 can alter the extent of flow restriction to change the bulk density of the extruded material as the material is continuously extruded.

Preferably, the flow restriction element 43 can adopt several positions which, as a group, enable the flow restriction element 43 to be adjusted to restrict the flow of material through the flow restriction element 43 as much or as little as desired. For example, in a preferred embodiment of the invention, the flow restriction element 43 may be adjusted from a position in which the flow restriction element 43 does not restrict the flow of material through the extrusion chamber 15 at all, to a position in which the flow restriction element substantially restricts the flow of material through the extrusion chamber. In a most preferred embodiment, the adjustable flow restriction element 43 can adopt a position and be adjusted between positions in a continuum of uniquely flow restrictive positions.

The adjustable flow restriction element 43 includes means for adjusting the flow restriction element 43 so the flow restriction element may be adjusted between uniquely restrictive positions to change the bulk density of the extrudate. In a preferred embodiment, the means for adjusting the flow restriction element 43 is located external to the extruder 11 so the flow restriction element may be adjusted while the extruder is in operation without having to stop and open the extruder.

Referring now to FIGS. 2 and 3, a preferred embodiment of the adjustable flow restriction element 43 is shown. The adjustable flow restriction element 43 is formed of a cylindrical fixed plate component 47, a cylindrical movable plate component 49 located abutting the fixed plate 47 which is rotatable relative to the fixed plate 47, and an actuator 51 for rotating the movable plate 49 relative to the fixed plate 47. As shown in FIG. 1, the fixed plate 47 and the movable plate 49 are jointly located in the extruder 11 between the tip 45 of the screw 17 and the die 35 positioned across the downstream flow of material through the extruder 11. Referring back to FIG. 2, the movable plate 49 and the fixed plate 47 have apertures 53 and 55, respectively, extending there-through which are aligned with the downstream flow of material through the extruder 11. As shown in FIG. 4, the actuator 51 is coupled to the movable plate 49 so the actuator 51 can rotate the movable plate 49 relative to the fixed plate

47 from a position in which each aperture 53 in the movable plate 49 minimally overlaps a respective aperture 55 in the fixed plate 47 through a series of unique relative aperture positions to a position in which each aperture 53 in the movable plate 49 is fully aligned with a respective aperture in the fixed plate 47. The extent which the flow restriction element 43 restricts the flow of material through the extruder can be controlled by adjusting the actuator 51 to position the movable plate 49 to set the apertures 53 and 55 at a desired degree of overlap.

Referring again to FIGS. 2 and 3, the fixed and movable plates 47 and 49 of the adjustable flow restriction element 43 and the extruder die 35 are secured in the extrusion chamber 15 by a die housing 57 which is secured in the extruder door 27. The die housing 57 is a cylindrical sleeve having a central portion 59, a flanged end section 61, and a threaded end section 63. The die housing 57 is positioned in the bore 65 which defines the extruder door chamber 33, with the bore 67 of the die housing coaxially aligned with the extruder door bore 65 to permit passage of extruded material through the bore 67 of the die housing. Die housing bolts 69 extend through the outer face 71 of the extruder door 27 to secure the die housing 57 in the door 27.

Referring now specifically to FIG. 3, the die housing 57 holds the movable and fixed plates 47 and 49 in position to extend across the downstream flow of material through the extruder. The die housing bore 67 has a counterbore 73 located in the flanged end section 61 of the die housing 57 which receives and holds the movable plate 49 positioned across the downstream flow of material through the extruder. As shown in FIG. 2, die housing bolts 69 extend through the die housing 57 and into threaded bolt holes 75 in the fixed plate 47 to secure the fixed plate against the flanged end section 61 of the die housing 57.

Referring again to both FIGS. 2 and 3, the movable plate 49 is held in the counterbore 73 abutting the fixed plate 47 so the movable plate 49 can freely rotate but cannot move linearly in the direction of the flow of material through the extruder. An axle 77 extends axially from the face 79 of the fixed plate 47 adjacent to the movable plate 49. A central aperture 81 of the movable plate 49 extends over the axle 77 of the fixed plate 47 so the movable plate 49 may rotate relative to the fixed plate 47 about the axle 77. As shown in FIG. 3, the outer edge 83 of the movable plate 49 is spaced slightly apart from the counterbore 73 by a gap 85 to permit the movable plate 49 to rotate freely in the counterbore 73 about the axle 77. The movable plate 49 is secured in the counterbore 73 by the abutting fixed plate 47 and a shoulder 87 formed by the counterbore 73. The fixed plate 47 and the shoulder 87 cooperatively prevent linear movement by the movable plate 49.

Referring again to both FIGS. 2 and 3, compressible O-rings 89 and 91 are provided to prevent material from seeping between the fixed and movable plates 47 and 49 as the material is extruded under pressure, thereby maintaining the rotatability of the movable plate 49. O-ring 89 is located in a groove 93 which extends about the circumference of the fixed plate 49, and forms a seal between the flanged end section 61 of the die housing 57, the extruder door bore 65, and the fixed plate 47. O-ring 89 prevents material being extruded from passing between the flanged end section 61 of the die housing 59, the extruder door bore 65, and the fixed plate 47 into the gap 85 between the counterbore 73 and the movable plate 49.

O-ring 91 is located in a circular groove 95 in the face 79 of the fixed plate 47 which abuts the movable plate 49. The

groove 95 is positioned between the outer edge 97 of the fixed plate 47 and the apertures 55 in the fixed plate. The O-ring 91 forms a seal between the movable plate 49 and the fixed plate 47 about the apertures 53 and 55 in the plates 47 and 49, preventing material being extruded from seeping from the apertures 53 and 55 between the fixed and movable plates 47 and 49 into the gap 85.

Referring now to FIG. 2, the actuator 51 is coupled to the movable plate 49 through a slot 99 in the die housing 57 so the actuator can rotate the movable plate 49. Preferably the actuator 51 is a linear actuator which has an extension 101 that is coupled with a pin 103 in pin receptacles 105 formed in the movable plate 49 at the outer edge 83 of the movable plate 49. The linear actuator 51 can move the extension 101 parallel to a line tangential to the edge 83 of the movable plate 49 to cause the movable plate to rotate. In a preferred embodiment the actuator 51 is a conventional linear actuator which is commercially available. For example, a preferred linear actuator is Magnetic Model Max 31 Linear Actuator available from Magnetic Corp. Olney, Ill.

The actuator 51 is preferably positioned over the extruder door 27 extending through the top 107 of the extruder door 27 with its extension 101 passing through the die housing 57 to the pin receptacles 105. An actuator support 109 is secured to the top 107 of the extruder door 27 with actuator support bolts 11. The actuator support 109 has two legs 113 which extend upwards from the extruder door, across which a support crossbar 115 is secured with crossbar bolts 117. The actuator 51 is suspended from the support crossbar 115 by a bolt 121 which couples a crossbar suspension bolt receptacle 123 extending from the bottom of the crossbar to suspension bolt receptacles 125 extending from the top of the actuator 51.

As shown in FIG. 4, a downwardly extending arm 127 is coupled to the actuator 51 positioned to extend through an actuator opening 129 in the extruder door 27. The actuator opening 129 extends transversely from the top 107 of the extruder door 27 to the extruder door bore 65 offset from the center of the extruder door bore 65. The actuator arm 127 extends through the actuator opening 129 to the extension 101 which is coupled to the arm 127 with an extension bolt 131 (shown in FIG. 2). The extension 101 extends from the arm 127 through the slot 99 in the die housing 57 to be coupled to the pin receptacles 105 of the movable plate 49.

Upon activation, the actuator 51 moves the extension 101 linearly in a direction tangential to the outer edge 83 of the movable plate 49. The movement of the extension 101 causes the movable plate 49 coupled to the extension 101 to rotate in a direction dictated by the movement of the extension 101. Rotation of the movable plate 49 changes the total area of overlap between the apertures 53 of the movable plate 49 and the apertures 55 of the fixed plate 47 by moving the apertures 53 of the movable plate 49 relative to the apertures 55 of the fixed plate 47. Restriction of the flow of material through the fixed and movable plates 47 and 49 may be increased or decreased by causing the actuator 51 to rotate the movable plate 49 in an appropriate direction to increase or decrease the overlapping area of the apertures 53 and 55.

Preferably, the apertures 53 and 55 are shaped so that the amount of overlap between the apertures 53 and 55 may be gradually increased or decreased by movement of the movable plate 49 relative to the fixed plate 47. In one embodiment of the invention, the apertures 53 and 55 have a wedge-shape cross-section. In a more preferred embodiment of the invention, the apertures 53 and 55 have a teardrop-shape cross-section.

Referring again to FIGS. 2 and 3, the extruder die 35 is located and removably secured in the threaded end section 63 of the die housing 57 by a die nut 133 threadably coupled to the threaded end section 63 of the die housing. The die 35 is a cylindrical sleeve having an end wall 135 through which the die orifice(s) 37 extend and a flange 137 at a flange end 139 of the die 35 which is opposite from the end wall 135. The die 35 is positioned with the flange end 139 abutting the threaded end section 63 of the die housing 57 with the die nut 133 threadably coupled to the threaded end section 63 of the die housing and gripping the flange 137 of the die 35 with a lip 141 to secure the die 35 in the die housing 57. In a preferred embodiment, the die 35 is properly positioned in the die housing bore 67 with a locator pin 143 extending from the threaded end section 63 of the housing 57 which is received in a groove (not shown) in the die 35.

The die 35 may be removed from the die housing 57 by unscrewing the die nut 133 from the threaded end section 63, and a new die may be secured in the die housing 57 by locating the flange end 139 of the new die 35 against the threaded end section 63 of the die housing 57 and screwing the die nut 133 onto the threaded end section 63 so the lip 141 grips the flange 137 of the new die.

In a particularly preferred embodiment of the invention, shown schematically in FIG. 5, means for measuring the bulk density 145 of material extruded from the extruder is positioned to receive and measure the bulk density of a portion of the material extruded from the extruder 11. Preferably, the means for measuring the bulk density is a conventional, commercially available device such as an apparatus for weighing a constant volume of material. For example, the means for measuring the bulk density may be a sample collecting container such as a bucket, a can, or a beaker which is periodically dipped in the stream of extruded material after the material is cut by the extruder knife, a scraper which scrapes across the top of the sample collecting container to level the extruded material in the sample collecting container to bring the material in the sample collecting container to a fixed volume, and a scale for weighing the sample collecting container containing a fixed volume of the extruded material. Most preferably, the means for measuring bulk density 145 is capable of automatically measuring the bulk density of material extruded from the extruder at set intervals of time.

The means for measuring the bulk density 145 is communicatively coupled to means for providing feedback 147 from the means for measuring the bulk density 145 to the actuator 51 (or other means for moving the movable component of the flow restriction element 43). The means for providing feedback 147 may be any means capable of transmitting the measured bulk density from the means for measuring the bulk density 145 to the actuator 51, including mere wiring, or any means of electronically or mechanically transferring the measured bulk density data. In a preferred embodiment, the means for providing feedback 147 is a data processing system which is communicatively coupled between the means for measuring the bulk density 145 and the actuator 51, and has a memory for storing and displaying a series of bulk density measurements from said means for measuring the bulk density 145. Most preferably, the means for providing feedback 147 automatically provides feedback from the means for measuring bulk density 145 to the actuator 51 (or other means for moving the movable component of the flow restriction element) each time the means for measuring bulk density 145 automatically measures the bulk density of an extrudate.

In a most preferred embodiment, the actuator 51, or other means for moving the movable component of the flow

restriction element 43, is structured and arranged to automatically move the movable component of the flow restriction element 43 relative to the fixed component of the flow restriction element in response to bulk density feedback provided by the means for providing feedback 147 from the means for measuring bulk density 145. For example, the linear actuator 51 described above may automatically move the movable plate 49 relative to the fixed plate 47 in response to bulk density input from a data processing system, where the data processing system receives the bulk density data from a means for measuring bulk density.

In another embodiment of the invention, as shown in FIG. 6, a cross-sectional view of a die housing 57, a die 35, and a piston-valve like embodiment of the adjustable flow restriction element 43 is shown. The die housing 57 and the die 35 may be located in the extruder by being secured in the extruder door as described above with respect to the previous embodiment. The adjustable flow restriction element 43 has a fixed component 163 and a movable component 165 which cooperatively can be adjusted to restrict the flow of material through the die housing 57 and the extruder in which the die housing is located.

The fixed component 163 has a substantially cylindrical rod portion 167 and an annular ring portion 169 extending about the rod portion 167 and being coupled to the rod portion 167 with spokes 171 which extend radially from the rod portion 167 to the ring portion 169. The ring portion 169 of the fixed component 163 is located in the counterbore 73 of the die housing 57 with the rod portion 167 extending coaxially partway through the bore 67 of the die housing 57. A flow channel 173 through which material may flow through the die housing 57 extends about the rod portion 167 in the die housing between the rod portion 167 and the bore 67 of the die housing.

The spokes 171 support and hold the rod portion 167 in its coaxial position in the die housing bore 67 when the ring portion 169 is located in the counterbore 73. Flow apertures 175 are located between the spokes 171 so material may flow between the rod portion 167 of the fixed component and the ring portion 169 into the flow channels 173. Preferably, the fixed component has three spokes 171 located at 120° angles relative to each other about the rod portion 167.

The movable component 165 is an annular ring which has a central aperture 177 through which extruded material may flow and which may be positioned to receive a flow blocking end 179 of the rod portion 167 of the fixed component 163. The annular ring of the movable component 165 also has a lip 181 which forms a shoulder 183 which the flange end 139 of the die 35 abuts. The die nut 133 threadably couples the threaded end section 63 of the die housing 57 to secure the die 35 and the movable component 165 in the die housing 63. A locking ring 185 is threadably coupled to the die nut 133 to prevent the die nut 133 from unscrewing from about the threaded end section 63 of the die housing 57 under the pressure exerted as material is extruded through the die housing 57.

The movable component 165 may be moved linearly relative to the flow blocking end 179 of the rod portion 167 to adjust the degree that the flow blocking end 179 is located in the central aperture 177 of the movable component 165, thereby adjusting the degree which the flow restriction element 43 blocks the flow of material through the extruder. The movable component 165 is moved by screwing or unscrewing the die nut 133 about the threaded end section 63 of the die housing 57 to move the die 35 towards or away from, respectively, the fixed component 163. Slots 187 and

189 are provided in the die nut 133 and the locking ring 185, respectively, so that a spanner wrench may be inserted into the slots 187 and 189 to enhance the ease of screwing or unscrewing the die nut 133 about the threaded end section 63.

As the die nut 133 is screwed further into the threaded end section 63 of the die housing 57, the die 35 and the movable component 165 are moved toward the flow blocking end 179 of the rod portion 167 of the fixed component 163, and the flow of material through the fixed and movable components 163 and 165 is increasingly restricted. As the die nut 133 is unscrewed about the threaded end section 63 of the die housing 57, the die 35 and movable component 165 are moved away from the flow blocking end 179 of the rod portion 167, and the flow of material through the fixed and movable components 163 and 165 is decreasingly restricted. The die 35 and the movable component 165 are moved away from the flow blocking end 179 of the rod portion 167 by pressure from the material being extruded when the die nut 133 is unscrewed.

Preferably the central aperture 177 in the movable component 165 and the flow blocking end 179 of the rod portion 167 of the fixed component 163 are structured to be mated together so the flow of material through the central aperture 177 will incrementally increase as the movable component 165 is moved away from the fixed component 163. In a preferred embodiment, the flow blocking end 179 is frusto-conically shaped, and the central aperture 177 has a flared section 191 facing the fixed component 163 which matingly receives the frusto-conical flow blocking end 179 of the rod portion 167. Most preferably, the diameter of the flared section 191 of the central aperture 177 is wider than the diameter of the rod portion 167 at the face 193 of the movable component 165 which faces the fixed component 163, and is narrower than the diameter of rod portion 167 at the neck 195 of the flared section 191, enabling the frusto-conical flow blocking end 179 of the rod to matingly fit in a portion of the flared section 191. As the movable component 165 is moved relative to the fixed component 163 the edges 197 and 199 of the flared section 191 and the flow blocking end 179, respectively, gradually separate, thereby gradually increasing or decreasing the extent the flow restriction element 43 restricts the flow of material there-through.

The embodiments of the adjustable flow restriction element 43 described above are the preferred embodiments of the flow restriction element 43, however, the invention is not intended to be limited to these embodiments. The adjustable flow restriction element 43 may be any apparatus which may be located in an extruder near the die of the extruder and which may be structured and arranged to adopt a plurality of positions which restrict the downstream flow of material through the extruder, where each position of the plurality of positions is uniquely restrictive, and where the flow restriction element is structured and arranged to be adjustable between each of the plurality of positions as material flows through the extruder. For example, the adjustable flow restriction element may be a sluice gate capable of assuming a number of positions partially extending across the extruder chamber.

The adjustable flow restriction element 43 may also be one of several different types of valves seated in the extruder near the extruder die positioned to restrict the flow of material through the extruder chamber. For example, the adjustable flow restriction element may be a piston valve, a globe valve, or a check valve. Typically the valve will have a valve seat, a valve stopcock which is movable relative to

the valve seat to assume a plurality of unique flow restrictive positions, and a means for moving the valve stopcock relative to the valve seat to adjust the valve stopcock between the plurality of unique flow restrictive positions.

Referring again to FIG. 1, to control the bulk density of an extruded food material in accordance with the process of the present invention, a food material mixture to be extruded is continuously fed into the inlet 23 of an extruder 11 having an adjustable flow restriction element 43 located therein, and is continuously extruded through the extruder 11 to form an extrudate. The food material mixture may include farinaceous and proteinaceous materials, as well as other desired ingredients, and may be preconditioned and moisturized with steam and water before being placed in the extruder.

After being deposited in the extruder 11 through the extruder inlet 23, the extruder screw(s) 17 advance the food mixture mass through the extruder 11 towards the adjustable flow restriction element 43 and the extruder die 35 while providing shear and pressure to the food-mixture. Heat may be supplied by the steam jackets 21 to the extruder barrel 13 to cook the food mixture as it proceeds through the extruder 11. The food material mixture is plasticized into a flowable mass by the combination of shear, temperature, and pressure as it proceeds through the extruder 11.

As the food material mixture is advanced through the extruder 11 the flow restriction element 43 blocks the flow of the food mixture through the extruder to the extent that the flow restriction element is positioned to restrict an area in the extrusion chamber 15 through which the food material mixture may flow. The level of energy imparted to the food material by the extruder screw 17 directly corresponds to the degree of restriction of the area by the flow restriction element 43 through which the food material may flow.

The extent of expansion of the extruded food material, and therefore the bulk density of the extrudate, is determined in part by the level material imparted to the food material by the extruder screw. Elevated levels of energy imparted to the food material by the screw as a result of a relatively greater degree of restriction of food material flow through the extruder cause the food material to expand more upon extrusion than relatively lower levels of energy imparted to the food material when the flow of food material through the extruder is relatively less restricted. A relatively unexpanded food material extrudate has a greater bulk density than a food material extrudate which is significantly expanded.

The bulk density of the extrudate, therefore, is controlled by mechanically controlling the overall area in the extruder proximate to the extruder outlet or extruder die 35 through which the food material mixture can flow with the adjustable flow restriction element 43. The overall area in the extruder proximate to the extruder outlet or extruder die 35 may be increased or decreased by adjusting the flow restriction element 43 to increase or decrease the bulk density of the extrudate. Preferably the adjustable flow restriction element 43 can be used to mechanically control the overall area by mechanically controlling the area of an aperture through which the food material mixture can flow through the extruder.

After flowing through the adjustable flow restriction element 43, the food material mixture enters the extrusion chamber between the flow restriction element 43 and the die 35 where it collects prior to extrusion through a die orifice 37. The food material mixture is then extruded through a die orifice 37 under pressure from further food material entering the extrusion chamber between the adjustable flow restriction element 43 and the die 35 to produce an extrudate,

which is cut to a desired size with a cutting blade (not shown). The extrudate is not particularly subject to variations in diameter, length, or width since restriction for the purpose of controlling the bulk density of the extrudate occurs prior to being extruded through the die 35.

In a preferred embodiment of the present invention, samples of the cut extrudate are periodically measured to determine the bulk density of the extrudate by periodically weighing a constant volume of the cut extrudate. Preferably, constant volume samples of the cut extrudate are collected in a sample collecting container large enough to collect a sample of reproducible volume. Each constant volume sample is weighed to determine the bulk density of the extrudate material. Most preferably, the samples of extrudate are automatically collected, and the bulk density of the collected samples is automatically measured.

Using the measured bulk density of the samples, the bulk density of the extrudate can be controlled by adjusting the adjustable flow restriction element 43. In one embodiment of the invention, the bulk density of the extrudate is controlled by utilizing the flow restriction element 43 to maintain the bulk density of the extrudate at a predetermined level of bulk density while maintaining a fixed formulation of continuously extruded food material. A fixed formulation of food material may have inherent bulk density variations as the food material is extruded through the extruder 11, and the flow restriction element 43 may be used to mechanically adjust the overall area in the extruder proximate to the die 35 through which the food material may flow to compensate for these variations and maintain the bulk density of the extrudate at a predetermined level.

To maintain the bulk density level of an extruded food material at a predetermined bulk density level, the food material is continuously extruded through the extruder 11 to form an extrudate, and the bulk density level of the extruded food material is measured, preferably automatically. The measured level of bulk density of the extruded food material is compared with the predetermined bulk density level to determine whether the measured bulk density level is substantially equivalent to the predetermined bulk density level, again, preferably automatically. The overall area in the extruder proximate to the die 35 is then mechanically adjusted with the flow restriction element 43 until the measured level of bulk density of the extruded food material is substantially equivalent to the predetermined level of bulk density, provided the measured level of bulk density is not already substantially equivalent to the predetermined level of bulk density. These steps are preferably repeated at frequent intervals to ensure that the extruded food material remains at the desired predetermined level of bulk density.

In another embodiment, the bulk density of the extrudate of a continuously extruded food material is controlled by utilizing the flow restriction element 43 to alter the bulk density level by increasing or decreasing the bulk density level of the extrudate from a first bulk density level to a second bulk density level. As the food material is continuously extruded through the extruder 11 to form an extrudate, the overall area in the extruder proximate to the die 35 is mechanically adjusted with the flow restriction element 43 to alter the bulk density level of the extrudate from the first bulk density level. The overall area is adjusted with the flow restriction element so the bulk density level changes from the first bulk density level towards the desired second bulk density level, for example, the overall area may be decreased with the flow restriction element 43 if the desired second bulk density level is less than the first bulk density level.

The resulting level of bulk density of the extruded food material caused by adjusting the overall area in the extruder

proximate to the die with the flow restriction element 43 is measured, preferably automatically, to determine the effect of the change of the overall area on the bulk density level. The measured resulting bulk density level of the extrudate is then compared with the desired second bulk density level to determine if the measured resulting bulk density level is substantially equivalent to the desired second bulk density level, again, preferably automatically. The overall area in the extruder proximate to the die is then mechanically adjusted with the flow restriction element 43 to change the bulk density level of the extrudate from the measured resulting bulk density to the second bulk density level, provided that the measured resulting bulk density level is not already substantially equivalent to the second bulk density level. The steps of measuring the resulting bulk density level, and adjusting the overall area with the flow restriction element 43 are repeated until the measured resulting bulk density level is substantially equivalent to the second bulk density level.

It will be appreciated by those skilled in the art that various changes may be made in the invention as disclosed without departing from the spirit of the invention. The invention is not to be the specifics of the disclosed embodiments, but rather is to be limited only by the scope of the appended claims and their equivalents.

What is claimed is:

1. A process for mechanically controlling the bulk density of an extrudate of a continuously extruded food material, comprising:

continuously extruding a food material through an extruder outlet to form an extrudate of generally uniform predetermined shape, and

mechanically controlling an overall area within said extruder proximate to said extruder outlet through which said food material can flow through said extruder to control the bulk density of said extrudate while maintaining the shape.

2. The process of claim 1 wherein mechanically controlling said overall area within said extruder through which said food material can flow comprises mechanically adjusting the area of an aperture through which food material can flow through said extruder.

3. The process of claim 1 wherein said bulk density of said extrudate is controlled by maintaining the bulk density of said extrudate at a predetermined level of bulk density while maintaining a fixed formulation of said food material.

4. The process of claim 3 wherein said bulk density of said extrudate is maintained at a predetermined level of bulk density by mechanically adjusting said overall area in said extruder through which said food material can flow in response to inherent bulk density variations in said food material being extruded.

5. The process of claim 4 wherein said overall area is mechanically adjusted in response to inherent bulk density variations in said food material being extruded by measuring level of bulk density of a sample of extruded food material, comparing the measured level of bulk density with said predetermined level of bulk density, and mechanically adjusting said overall area in said extruder through which said food material can flow until said measured level of bulk density is substantially equivalent to said predetermined level of bulk density.

6. The process of claim 1 wherein said bulk density of said extrudate is controlled by altering the level of bulk density

of said extrudate from a first level of bulk density to a second level of bulk density.

7. The process of claim 6 wherein said bulk density of said extrudate is altered from a first level of bulk density to a second level of bulk density by mechanically adjusting said overall area in said extruder through which said food material can flow.

8. The process of claim 7 wherein said overall area is mechanically adjusted to alter said bulk density of said extrudate from a first level of bulk density to a second level of bulk density by mechanically adjusting said overall area to change the bulk density level of said extrudate from said first level of bulk density, measuring a resulting level of bulk density of a sample of extruded food material after mechanically adjusting said overall area, comparing the measured resulting level of bulk density with said second level of bulk density, and mechanically adjusting said overall area in said extruder through which said food material can flow until said measured resulting level of bulk density is substantially equivalent to said second level of bulk density.

9. The process of claim 8 wherein said resulting level of bulk density of said extruded food material is automatically measured, said measured resulting level of bulk density is automatically compared with said second level of bulk density, and said overall area in said extruder through which said food material can flow is automatically mechanically adjusted until said measured resulting level of bulk density is substantially equivalent to said second level of bulk density.

10. A process for mechanically controlling the bulk density of an extrudate of a continuously extruded food material, comprising:

continuously extruding a food material through an extruder outlet to form an extrudate of generally uniform predetermined shape;

mechanically controlling an overall area within said extruder proximate to said extruder outlet through which said food material can flow through said extruder to control the bulk density of said extrudate while maintaining the shape;

automatically measuring said bulk density of said extruded food material;

automatically comparing said measured level of bulk density with a predetermined level of bulk density; and automatically adjusting said overall area in said extruder through which said food material may flow until said measured level of bulk density is substantially equivalent to said predetermined level of bulk density.

11. A process for mechanically controlling the bulk density of an extrudate of a continuously extruded food material of generally uniform predetermined shape, comprising:

continuously extruding a food material through an extruder having a screw and an extruder die to form an extrudate; and

mechanically adjusting a variable flow restriction element located within said extruder between a tip of the screw and the extruder die through which said food material can flow to control the bulk density of said extrudate while maintaining the shape.

* * * * *

EXHIBIT F

[54] **PROCESS FOR PREPARING A
DEHYDRATED PROTEIN PRODUCT FROM
ANIMAL MATTER**

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71/19; 71/64 D; 426/453; 426/473; 426/518;
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[58] Field of Search 426/285, 641, 643, 644,
426/646, 657, 453, 471, 473, 518, 519, 520, 805,
807; 71/15, 16, 19, 20, 22, 64 D, 64 DC

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Primary Examiner—Arthur L. Corbin

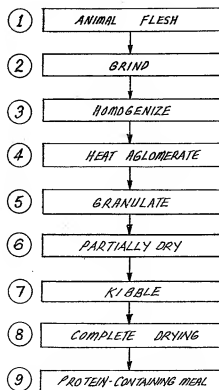
Attorney, Agent, or Firm—Richards, Harris & Medlock

[57]

ABSTRACT

A process for the production of dehydrated foodstuffs, feedstuffs or plant fertilizers includes the following steps: (a) preparing protein-containing animal matter to a particulate size acceptable to homogenizing equipment; (b) subjecting the comminuted matter to ultra homogenization; (c) heating the resultant homogenate to a temperature of between about 50° C. and 85° C. to agglomerate the protein; (d) granulating the agglomerate; (e) drying the granules at a temperature not greater than 95° C. until their moisture content is within the range of about 20% to about 50% by weight; (f) passing the partially dried granules through a mincer to form kibbles; (g) drying the kibbled material to achieve a moisture content not more than 8% by weight.

8 Claims, 2 Drawing Figures



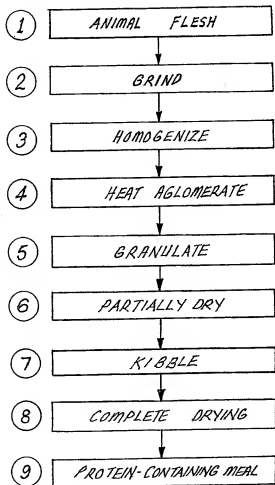
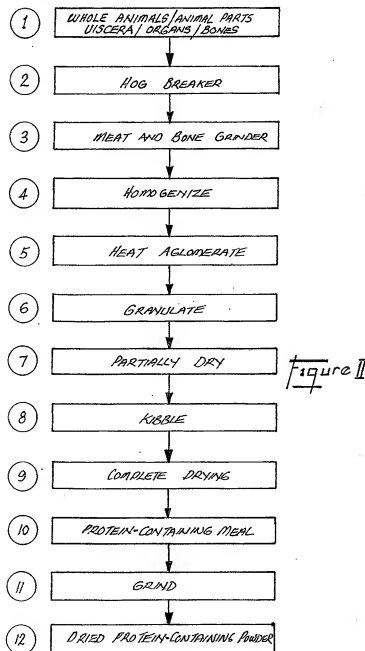


Figure I



PROCESS FOR PREPARING A DEHYDRATED PROTEIN PRODUCT FROM ANIMAL MATTER

This invention relates to a process for manufacturing 5 dehydrated foodstuffs, feedstuffs or plant fertilizers. In one aspect of this invention it relates to the use of the process to prepare protein-containing foodstuffs for human food applications and can be used either in a dehydrated or rehydrated form. Another aspect relates to the use of the process to prepare protein-containing 10 meals for use in pet foods in either a dehydrated or rehydrated form. A further aspect of the invention relates to the use of the invention in preparing animal feedstuffs. In still another aspect of the invention it relates to a method for treating meat packing plant wastes as an alternative to conventional rendering. This last application includes the preparation of plant fertilizers from, for example, the bones of slaughtered animals.

In a present day world which is continually burdened 20 by escalating costs there is a need to develop processes and systems that lower the costs of preserving, storing and transporting food, in particular, proteins. This need is further felt in a world where food surpluses can exist in one area while in another area there are food shortages. The costs of preserving, storing and transporting of food contribute materially to the selling price of foodstuffs and can put the price beyond the means of people in under developed countries with a low standard of living where food shortages exist. Still further 30 any reduction in the volume and/or weight of foodstuffs, feedstuffs or fertilizers will materially reduce the storage freight and handling charges incurred in the storage and transportation of these materials.

There is also a need to preserve such materials by 35 a means which does not require refrigeration which makes possible their use in under developed areas of the world where such modern day facilities do not exist. Further, there is a need to reduce the energy requirements of processing, storing and transporting foodstuffs in a world which is running out of fossil fuels.

In a world in which people are concerned about preserving the environment and in providing pure, uncontaminated and unadulterated food, there is a need 45 for food preserving and preparing processes that do not require the or at the very least minimise the need for addition of chemical additives. Generally the process of this invention does not require chemical additives such as emulsifiers, to achieve a satisfactory performance of this invention. The addition of antioxidants, as commonly used in the preparation of dehydrated proteins is however contemplated.

Accordingly it is an object of this invention to alleviate at least some of the problems enumerated. It has been proposed to precook meat and other protein-containing material, mince grind or otherwise particulate 50 the meat or other material and then dry the cooked particulate material.

These processes result in final products whose characteristics such as taste and texture are unacceptably 60 removed from those of the meat from which the final product was derived.

Further, prior proposals teach unacceptably high temperatures which cause early agglomerations of the protein and the separation of fat and natural juices from the meat. The fat so separated is either lost or must be recovered and re-incorporated into proteinaceous matter at a later stage.

The present invention however does not suffer from these disadvantages as the animal protein-containing material is ultra homogenized before any application of heat. The proteins are thus not agglomerated prior to any mincing or homogenizing of the material. Further, the present invention specifies the need for ultra homogenization (as herein defined) while prior proposals teach only a very much larger particle size.

According to the present invention therefore, there is provided a process for the manufacture of dehydrated foodstuffs, feedstuffs or plant fertilizers including the steps of:

(a) subjecting raw or uncooked, or substantially raw or uncooked, protein-containing animal matter to ultra homogenization;

(b) heating the resulting homogenate to form an agglomerate;

(c) drying the agglomerate to form particulate foodstuffs, feedstuffs or fertilizers.

Further according to this invention there is provided a process for the production of dehydrated foodstuffs, feedstuffs or plant fertilizers including the following steps;

(a) preparing protein-containing animal matter to a particulate size acceptable to the homogenizing equipment;

(b) subjecting the comminuted matter to ultra homogenization;

(c) heating the resultant homogenate to a temperature of between about 50° C. and 85° C. to agglomerate the protein in the homogenate;

(d) granulating the agglomerate;

(e) drying the granules at a temperature not greater than 95° C. until their moisture content is within the range of about 20% to about 50% by weight;

(f) passing the partially dried granules through a mincer to form kibbles;

(g) drying the kibbled material to achieve a moisture content not more than 8% by weight.

Preferably the temperature of the particles is kept below 60° C. for the purposes of attaining optimum rehydration properties.

While major uses of the present invention include the preparation of foodstuffs for humans and feedstuffs for animals the process of this invention may also be used to prepare animal derived plant fertilizers. To this end bones and/or other substantially proteinaceous material derived from animals may be treated as described to form a particulate material which when spread onto the ground or incorporated therein will readily take up moisture and rehydrate and then decompose to provide plant nutrients.

In this specification reference is made to the processing of proteinaceous animal matter. By "proteinaceous animal matter" it is meant any material, including flesh, organs, viscera, skin or bones, or any combination thereof. Reference to animals includes reference to mollusk, shell fish, crustacea, fish, plancton, amphibia, reptiles, mammals and insects. The aforementioned list of animals is not considered to be complete but only representative of animals whose matter may be processed by this invention. The kibbles produced by step (f) above typically (although not exclusively) are of a size not greater than about 1/4 inch (average of measurements in the three dimensions) and are rough in form and texture to thereby have a large surface area to facilitate the drying step (g). The kibbles, when dried, can be powdered by grinding to produce a powdered product

which may be more acceptable in soups or for incorporating into other processed foods or feedstuffs or fertilizers.

The word kibbled is defined in the Oxford English Dictionary as "To bruise or grind coarsely".

This definition largely explains the physical action necessary to produce the desired kibbled form of the end product. The action of kibbling as taught by the described process of this specification is necessary to break open the case hardened film of protein which occurs in the early stages of drying on the gelled particles. This assists the drying of the particles in the second stage of drying and the development of a cellular structure within the particles. This cellular structure is necessary to achieve good rehydration properties of the dried kibbles. Kibbling also effects an irregular shaped particle which is desirable in achieving a "clunky" appearance to the rehydrated meat particle.

In the drying of the material, for example at steps (e) and (g) above, it should be born in mind that the temperature of the material being dried will be measurably lower than that of the drying medium. This is so because the evaporation of the moisture in the material will cause a heat loss to the material not fully compensated for by the acquisition of heat from the drying medium.

While this invention teaches that effective storage of dehydrated protein-containing material can be achieved in certain instances with a moisture content as high as 8% by weight, it has been found that to ensure effective preservation against degradation during long term storage at ambient temperatures, a moisture content of 5% by weight or less seems desirable.

By the term ultra-homogenization it is meant that the homogenization procedures of the process of this invention are exceptional when compared with commercial meat emulsions or homogenates as used in processed meat products such as sausages, luncheon meats and the like products.

The procedure of preparing the homogenate as described within the specification is exceptional, in that the meat tissues are more finely homogenized than commercial meat emulsions.

In establishing the extent to which the described process more finely homogenizes than standard commercial meat emulsions, an electron micrographic study was conducted on a beef homogenate prepared as described and compared with samples taken from commercially produced emulsified meat products. The result showed that the beef homogenate prepared by the method described herein, had a particle size ranging from 0.4 to 3.0 microns, whereas the commercial meat emulsion ranged from 3.7 to 18 microns.

Now whereas the generally accepted practice in making meat emulsions is to retard frictional heating, which occurs during emulsification by adding an amount of ice or cold water to the meat, in the process of this invention this heat build up is desirable and should be achieved as rapidly as possible to retard biodegradation. In practice, using a Fryma colloid mill, 3 passes of the meat through the mill are required to attain the degree of homogenization required. The temperature of the meat emulsion existing the colloid mill on the final pass typically ranges from about 55° C. to 65° C. and relates to the temperature of the meat at the start. Meat in a frozen, chilled or fresh state has been used successfully in the process.

A further advantage of the process is that lower grades of meat such as neck trimmings and the like can be used. The procedure of ultra homogenization reduces all tendons, skin and connective tissues to a minute particle size and these are blended with the muscle tissues. Upon heat agglomeration and drying of the processed meat these tissues are indistinguishable from the muscle tissues. This has the value of improving the digestibility of the meat and improving the economics by upgrading lower value meat trimmings.

Because of the fine homogenization the product of the process should be of value for dietetic use where easy digestion of the meat is desirable.

The dehydrated meat protein-containing products produced by this process are characterised by their ability to be stored without refrigeration and to rehydrate for use in processed meat products, convenience foods and the like. The invention also provides a process for dealing with meat works waste to prepare meat meals as an alternative to conventional rendering and can also have application with poultry and fish waste.

One form of the invention will now be described although it must be appreciated that such description is by way of example only and that the values and ranges may be varied and that variations may be made in the process without departing from the spirit and scope of this invention as may be ascertained from this specification.

The raw (or substantially raw) deboned animal flesh is cut up and ground through a meat mincing machine to a size which is suitable for acceptance by the homogenizing equipment. A standard commercial meat mincing machine is suitable for this purpose. The size of the ground meat particle is dependent upon the size of the homogenizing equipment; large scale machines can accept larger meat particles. The animal flesh is then subjected to ultra homogenization which breaks down the fibrous tissue and emulsifies the associated fats. The resulting homogenate occurs as a smooth, creamy, liquid to semi-solid substance. For small scale production a commercial Waring Blender has been used. This machine, a model 91-265, is capable of generating impeller speeds of up to 20,000 revolutions per minute. On a larger scale commercial meat emulsifying machines with fine settings can achieve the degree of homogenization required. Such machines are in common use in the processed meat industry for preparing sausages, luncheon meats, bologna and the like products. The ultra homogenized animal tissue is then subjected to heating to effect gelation of the meat proteins. The heating step can be achieved by a number of means, for example, a steam jacketed mixing pan, a steam heated extruder or a microwave oven. It is also anticipated that the frictional heat created during the homogenization step of the process could, in some circumstances, produce sufficient heat to effect gelation of the proteins. Also with some homogenizing equipment it is possible to apply steam to the body of the homogenizing chamber thereby providing a means of heating the homogenate to a temperature at which the meat proteins will agglomerate. It is desirable that during the heat agglomeration stage that the homogenate be agitated to effect uniform heating and to assist in preparing the aggregated proteins into a granular particulate form. The particulate granule size may be further adjusted to give the desired texture by passing the aggregate through a meat mincer or wet granulating machine. The size of the particle is a matter of choice and depends upon the

desired particle size required at rehydration. It has been found that a particle size of about $\frac{1}{4}$ " is suitable for most purposes. The gelled aggregated protein particles can then be subjected to drying. This can be effected by a variety of drying equipment such as fluid bed dryers, hot air drying ovens, microwave ovens and such like equipment. It is desirable that the product be dried to a final moisture content of less than 5% to ensure the stability of the end product on storage. The dried product can be further ground or powdered and screened to give the texture desired.

In the preparation of these protein-containing meals it is anticipated that combinations of tissues from various animal species could be used also, combinations of animal tissues with vegetable proteins and the inclusion of carbohydrates, cellulosic substances and vegetables, is further anticipated. Also the inclusion of seasonings and flavourings. A schematic layout of a typical processing system for producing the protein meals of this invention is shown in FIG. 1. of the accompanying drawings.

The product of the process of this invention gives excellent biological results. Example 12 illustrates typical bacterial count data. On storage properties shelf life tests have been carried out with accelerated test storage samples. These show that the dehydrated meats produced by this process remain in fresh condition, containing between 0 to 1.0 parts per million malonaldehyde on a 67% moisture basis which is the acceptable level for a fresh cooked meat product. Data is given in example 11 herein.

In preparing protein-containing meals from meat works wastes which contain bones, the comminution of the bone tissue is required to take place simultaneously with the ultra homogenization. This requires more processing steps; a schematic layout of the process is given in FIG. 2 of the accompanying drawings. Whole animals or animal parts or viscera or organs or bones etc., or combinations of these materials are passed through a hog breaker or prebreaker. These are heavy duty machines capable of breaking up animal bone and other tissues and are common to the rendering industry. From the hog breaker the comminuted material is then passed through a heavy duty grinding machine which is capable of handling bones, such a machine is a Weiler Grinder, a machine which is common to the meat and rendering industries. The ground waste is then subjected to ultra homogenization. Suitable equipment for this step would be the Reitz Disintegrator or a Jeffco mill which are both high speed combined grinders and emulsifiers. Following ultra homogenization the homogenate is then subjected to heating to effect agglomeration of the proteins and then to drying. This part of the process is similar to that described in the previous paragraph and detailed in FIGS. 1 and 2 of the drawings.

The temperature at which the gelation of the proteins is normally achieved is within a range of about 55° C. and 75° C. Drying temperatures should be kept low to reduce heat denaturation of the proteins but sterilisation requirements may necessitate elevating temperatures to achieve this, in particular, when dealing with animal wastes.

EXAMPLE 1

500 grams of lean beef was ground through a hand mincing machine fitted with a $\frac{3}{16}$ " cutting plate. The ground meat was then subjected to ultra homogenization in a Starmix Blender for $\frac{1}{2}$ minute. At this point the

meat was a smooth creamy texture. The homogenized meat was then transferred to a steam heated pan and heated with agitation until the protein-containing mixture agglomerated. Agglomeration commenced at a temperature of about 55° C. and satisfactory gel resulted when the temperature reached about 70° C. The agglomerated protein gel was then passed through a hand mincing machine fitted with $\frac{1}{4}$ " cutting plate and then dried in an oven whose temperature reached between 90° C. and 93° C. The moisture content of the finished dried powder was 7.7% and the yield was 158.7 grams of dry powder or 31.74% of the starting weight of the meat.

EXAMPLE 2

50 grams of dehydrated beef meal prepared as described in Example 1 was rehydrated with 100 grams of warm water, temperature 40° C.; a time interval of 15 minutes was allowed from the time of adding the water to the dehydrated meat for rehydration to occur. Little free water was observable after this period. 150 grams of meat, consisting of approximately 50% lean meat and 50% fat was ground in a hand grinder fitted with a $\frac{1}{4}$ " cutting plate. The ground meat was then blended together with the 150 grams of rehydrated meat and formed into Hamburger patties. The hamburger patties were then pan fried and resulted in firm textured hamburger having good flavour.

EXAMPLE 3

344 grams of chicken meat which included some chicken skin was ground through a hand mincing machine fitted with a $\frac{1}{4}$ " cutting plate. The ground chicken was then subjected to ultra homogenization in a Starmix blender for $\frac{1}{2}$ minute. The homogenate was then transferred to a steam heated pan and heated with agitation until a satisfactory agglomerate resulted. Gelation of the proteins commenced at about 55° C. and heating was continued until the temperature had reached 67° C. when a satisfactory gel had resulted. The gel was then dried in an oven at a temperature of from 90° C. to 93° C. until a satisfactory dry product resulted. The moisture content of the dry material was 6.85% and the yield was 130.14 grams or 37.74% of the starting weight of the chicken.

EXAMPLE 4

511 grams of fish (Terakihi) was cut into pieces about 1" in size and subjected to ultra homogenization in a Starmix blender. The homogenate was then transferred to a steam heated pan and heated until a satisfactory granular gel had resulted. The homogenate was stirred during the heat gelation step. The gelled granules were then dried in an oven at a temperature of 90° C. to 93° C. until a satisfactory dried product resulted. The moisture content of the dried product was 6.1% and the yield was 162 grams or 31.70% of the starting weight of the fish.

EXAMPLE 5

20 kilos of minced lean beef (90% visual lean) was passed through a Fryma colloid mill set at a fine gap for three passes. The temperature of the meat homogenate exiting the mill was 37° C. on the third pass. The homogenized meat was then heated gently in an electrically heated pan with continuous agitation until the meat proteins had agglomerated. The temperature reached 74° C. at the end of this operation. The agglom-

erated meat was then passed through a hand mincing machine to reduce the size of the gelled material to about $\frac{1}{4}$ " to $\frac{1}{2}$ " pieces. This was then placed in a fluid bed dryer having an inlet air temperature of about 60° C. On adding the charge to the fluid bed dryer the outlet air temperature fell to about 28° C. The semi dry material was removed from the dryer when the air exit temperature had reached about 40° C. then passed once more through the hand mincer. The moisture content was about 45 to 50% at this point. This procedure formed the semi dry meat into a kibble about $\frac{1}{4}$ " to $\frac{1}{2}$ " long. The kibble meat was returned to the fluid bed dryer until the outlet temperature had reached 58° C.

On analysis the sample gave the following data:

Moisture: 4.60%

Fat: 34.44%

Protein: 58.36%

The sample rehydrated satisfactory when mixed 1 part of dried meat to 2 parts of water.

EXAMPLE 6

45.4 kilograms of lean mutton was given one pass through a Fryma perforated disc mill model ML330 fitted with an 8 m.m. perforated disc. The mutton was then given two passes through the same mill fitted with a 2 m.m. perforated plate. Antioxidants, propyl gallate and citric acid were added in solution to the meat during the first milling operation. The temperature of the homogenate was 56° C. exiting the mill on the final pass.

The homogenate was then agglomerated in a steam tube cooker which consisted of a steam jacketed tube approximately 2 meters in length and 150 m.m. in diameter and containing within the tube an auger power by an electric motor.

Exiting the steam tube cooker the agglomerated meat had a temperature about 72°/75° C.

The agglomerate was then passed through a wet granulator which was fitted with a $\frac{1}{4}$ " perforated screen. The material was formed into a wet granular texture about $\frac{1}{4}$ " to $\frac{1}{2}$ " in size.

The wet granules were then fed into a Moa fluid bed dryer which had an inlet temperature of 58° C. on the inlet and 30° C. on the outlet. The granules were removed from the dryer when the moisture content was ranging from 22 to 25% and then passed through a hand grinder fitted with a $\frac{1}{8}$ " plate to form a kibble like texture. The kibbles were then returned to the Moa dryer and removed when the moisture content was below 5%.

EXAMPLE 7

39 kilograms of lean pork was processed in the manner described in Example 6.

EXAMPLE 8

50 kilos of frozen shark meat was cut into pieces about 3" to 4" in length then given one pass through the Fryma perforated disc mill, Model ML 330, fitted with an 8 m.m. perforated disc. Antioxidants, propyl gallate and citric acid were proportioned into the fish during this first pass. The homogenized fish was then given three passes through the Fryma fitted with a 2 m.m. perforated disc. Temperature of fish exiting Fryma on fourth pass was 40° C.

The fish was then agglomerated in a steam tube cooker and then transferred to a steam jacketed pan. The fish was gently heated until the moisture content was down to 56%. The wet gelled fish was then dried in

a fluid bed dryer and removed when the moisture content was reduced to about 2.0%.

EXAMPLE 9

5 kilos of beef liver was given 3 passes through a Fryma colloid mill, then heat agglomerated in an electric pan. The agglomerated liver was then passed through a hand mincer fitted with a $\frac{1}{8}$ " plate to granulate the gel. The granules were then dried in a fluid bed dryer.

EXAMPLE 10

Commercial grade whole fish consisting of a mixture of red cod (*phyculus bachus*) and Whiptail (*Macrurus nova zealandiae*) and containing all bones, viscera, fins and heads were chopped into pieces and passed 3 times through a Fryma Colloid Mill. The resulting homogenate was then heated in a microwave oven until the proteins had gelled. During the heating cycle, the homogenate was removed from the microwave oven and stirred to get uniform heating.

The temperature of the homogenate reached about 65° C. during the heating cycle. The gel was then passed through a mincing machine to form the gel into a granular particulate to facilitate drying. The wet gel particulate was then placed into a fluid bed dryer having an inlet air temperature of between 65° and 70° C. and dried until the moisture content was reduced from about 80% to about 40%. The partially dried material was then removed from the fluid bed dryer and kibbled as herein described in this specification. The resulting kibbles were returned to the fluid bed dryer and drying continued until the moisture content of the kibbles was less than 5%.

The product of this example was rehydrated in the ratio of about 1 part of dried fish kibbles to 3 parts of water and fed experimentally to mink.

In a similar experiment, the rehydrated fish kibbles were fed to domestic cats. In both cases the rehydrated product was acceptable to the animals.

EXAMPLE 11

The product of example 5 was rehydrated with water in the ratio of about 1 part dried beef kibbles to 3 parts of water.

The rehydrated beef kibbles were then fed to domestic dogs and domestic cats respectively. In both cases, the rehydrated beef kibbles were readily accepted by the animals.

EXAMPLE 12

10 kilograms of beef bones from the deboning operations of a meat works were broken in a Niven Pre-Breaker which reduced the bones to particles about less than $\frac{1}{8}$ " in size. The broken bones, together with the associated meat proteins, bone marrow and fat, were then passed through a Jeffco Plate Mill fitted with a $\frac{1}{8}$ " plate then for a further pass through a Jeffco fitted with an $\frac{1}{8}$ " plate.

During the passes through the Jeffco Mills, water was added to bone mixture to facilitate grinding. The moisture content of the resulting homogenate was 54.7%.

The homogenate was then heated in a steam jacketed pan until the mixture gelled. The gel was then passed through a mincing machine fitted with a $\frac{1}{4}$ " plate to break up the gel into discrete particles about less than a $\frac{1}{4}$ " in size. The product was then dried in a fluid bed

dryer having an inlet temperature of 70° C. until the moisture content was less than 8%. The product was then allowed to cool then ground in a hammer mill to form a granular to powder particulate having the characteristics of conventional meat and bone meal produced through rendering. The product of this example was applied to a garden plot as a fertilizer and soil conditioner.

T.B.A. ANALYSIS ON MEAT

I. METHOD

Method as set out in the schedule to this specification (Tarladgis et al, modified by Mahon). The meat samples in this case were in dehydrated form, i.e. 5 grams of dehydrated animal protein, equivalent to 15 gms rehydrated.

II. STANDARD CURVE

0, 3.5, 7.0 & 10.5 mls of 2×10^{-5} Molar T.E.P. were brought up to 50 mls with the acid solution and 5 mls sampled. This provided a series of 0, 0.5, 1.0, 1.5×10^{-6} gms malonaldehyde for optical density readings as in Steps 3, 4 & 5. Readings on the Varion Techtron Model 635 with double beam were, 0, 0.120, 0.240, 0.362. The response curve showed 4.17×10^{-6} grams malonaldehyde per unit of optical density.

III. RECOVERY

A duplicate 3.5 mls of 2×10^{-5} Molar T.E.P. were put through the whole distillation procedure and resulted in readings of 0.083 and 0.089 giving recoveries of 69% and 74% compared with 0.120 from the Standard Curve. The conservative figure of 69% recovery was used.

IV. CONSTANT

The Constant (K) to multiply optical densities by to get P.P.M. of malonaldehyde in the 5 gm samples is then,

$$K = \frac{4.17 \times 10^{-6}}{.69} \cdot \frac{10^6}{.5} \\ = 12.1 \text{ (compared with 11.6 for Mahon)}$$

V. P.P.M.

P.P.M. in Sample = Optical Density \times 12.1

VI. RESULTS

SAMPLE	P.P.M. (5 gms Dry)	P.P.M. (15 gms reconstituted)
No Antioxidant		
Beef 30 days at 40° C.	1.43	.48
Beef 40 days at 40° C.	1.43	.48

RESULTS

Product	Date Rec'd	Total Viable count per gram.	Staph. aureus per gram	Faecal coli per gram	Clostr. per fringens per gram	Bacillus Cereus per gram	Salmonella spp. per 25 gram.
Beef	16. 2. 78	44	100	—	20	100	absent
Beef	16. 2. 78	28	100	100	20	100	absent
Beef	21. 2. 78	70	—	—	20	100	absent
Beef	21. 2. 78	50	—	—	20	50	absent
Beef	21. 2. 78	16	—	—	20	50	absent
Chicken	21. 2. 78	1600	—	100	20	100	absent
Liver	21. 2. 78	115	—	100	20	100	absent
Heart	21. 2. 78	520	—	100	20	100	absent

Beef 60 days at 40° C. 1.57 .52

Antioxidant

Beef 40 days at 40° C. .85 .28

BACTERIOLOGICAL ANALYSIS

The bacteriological plate counts on the finished dehydrated products are very low and well within acceptable limits for foods of this type.

Typical analysis are as follows:

(a) BEEF

Total viable plate count on 5 batches gave readings of 44, 28, 70, 50 and 16 organism per gram.

(b) MUTTON

Total viable plate count on 1 batch gave a reading of 200 organisms per gram.

(c) CHICKEN

Total viable plate count on 1 batch gave a reading of 1600 organisms per gram.

(d) BEEF LIVER

Total viable plate count on 1 batch gave a reading of 115 organisms per gram.

(e) BEEF HEART

Total viable plate count on 1 batch gave a reading of 520 organisms per gram.

These are compared with the National Health Institute guidelines which consider that a total viable count of 1,000,000 organisms per gram as a tolerable level.

The following diagnosis of products of this invention was carried out with the results indicated.

DEHYDRATED MEAT PROJECT

1. To check microbiological levels of products
2. To enumerate specified organisms listed in National Health Institute Guidelines April, 1976.

METHODS

1. Total Viable Count: Aliquots of fluid from reconstituted product are mixed with Columbia agar and incubated at 20° and 37°.

2. *Staph. aureus*: Dilutions of reconstituted product inoculated to Baird-Parker medium.

3. Faecal Coli: M.P.N. using Maconkey broth, presumptive positives confirmed by additional tests.

4. *Clostridium perfringens*: Dilutions of reconstituted product inoculated to Egg Yolk Agar medium incubated anaerobically.

5. *Bacillus cereus*: Dilutions of reconstituted product inoculated to Egg Yolk Agar medium and suspect colonies confirmed biochemically and microscopically.

6. Salmonella exclusion: Enrichment media followed by a selective media and biochemical/serology tests as required.

Eight of the samples received have levels of bacteria that conform standards recommended by the National Health Institute.

The following are the Guidelines for maximum tolerances of microbiological levels in foods as specified by the National Health Institute, Department of Health, Wellington, New Zealand and dated in April 1976.

COOKED FOODS AND COOKED MEATS

(Includes frozen pre-cooked meals and all foods not necessarily receiving subsequent heating, e.g. International flight meals, frozen cooked seafoods, "Take-Away" foods.)

Total Viable Count—500,000/g.

Staphylococcus aureus (coagulase producing)—100/g.

Faecal Coliform—20/g.

Clostridium perfringens—100/g.

Bacillus cereus—100/g.

Salmonella—0/25 g.

SEMI-PRESERVED, THOUGH STILL PERISHABLE PRODUCTS

(Includes salted, cured or semi-preserved meat, fish and uncooked prepared seafoods, e.g. Fish fingers, crumbed seafoods, vacuum-packaged sliced meat products.)

Total Viable Count—1,000,000/g.

Staphylococcus aureus (coagulase producing)—100/g.

Faecal coliform—100/g.

Clostridium perfringens—100/g.

Bacillus cereus—1,000/g.

Salmonella—0/25 g.

SHELLFISH

(Standard as laid down by Shellfish Sanitation Bureau, F.D.A.)

Total Viable Count—500,000/g.

Faecal coliform—230/100 g.

Salmonella—0/25 g.

FROZEN RAW EGG PULP

Total Viable Count—1,000,000/g.

Salmonella—0/25 g.

FROZEN PASTEURISED EGG PULP

Total Viable Count—15,000/g.

Faecal coliform—100/g.

Salmonella—0/25 g.

(Regulation 154 of the Food and Drug Regulations (1973) for the Resazurin Test as described in the Ninth Schedule to these Regulations).

DESICCATED COCONUT

Salmonella—0/25 g.

DAIRY PRODUCTS

The Food and Drug Regulations (1973) contain requirements that control the microbiological standards for a range of dairy products.

Regulation	116	Pasteurised milk
"	117	Standard milk
"	118	Recombined milk
"	119	Flavoured milk
"	121	Non-fat milk
"	122	Milk beverages or milk shakes
"	128	Pasteurised cream
"	129	Reduced, pouring or sour cream
"	130	Recombined cream
"	141	Ice cream
"	142	Frozen confections

When subjected to the test described in the Sixth Schedule to these Regulations, 3 out of 5 replicate portions of 0.1 milliliter shall not give evidence of acid formation and gas formation as described in that Schedule.

YOGHURT

Faecal coliform—1/g.

Yeasts and moulds—20/g.

FOOD CONTAINERS

The Food Hygiene Regulations (1974), Regulation 17, Clause 3, Sub-Clause (b), contain requirements governing the microbiological limits for bottles, jars, or jugs, in that residual bacterial plate counts may not exceed

(i) More than 1/milliliter of containing capacity, or

(ii) More than 1/square centimeter of surface area.

SAMPLING

Select at random 10% or 20 units, whichever is the less, from a lot or consignment. Where a consignment is made up of a variety of component units, a minimum of three units from each variety is randomly selected. Wherever possible, unit samples of a product are submitted to the laboratory in the original unopened packaging, maintained in their physical state as at the time of sampling.

INTERPRETATION

With the exception of nil tolerance for *Salmonella*, where the non-compliance of 1 unit from a lot or consignment constitutes rejection, the following assessment is generally applied.

Where 5 or more units of the same variety from a lot or consignment are analysed, no more than 2 units shall exceed the maximum tolerance for microbiological levels stated in the Guidelines and no one unit shall exceed 10 times the maximum tolerance.

Further two (2) samples of meat dehydrated in accordance with this invention have been analysed as follows:

Sample Identification	Beef	Mutton
Total Aerobic Plate Count/gm.	100	200
Total Coliform/gm.	10	10
Faecal Coliform/gm.	10	10
<i>Salmonella</i> group/gm.	100	100
<i>Clostridium Perfringens</i> /gm.	100	100
<i>Staphylococcus aureus</i> /gm.	100	100
<i>Bacillus cereus</i> /gm.	100	100

SCHEDULE

DETERMINATION OF RANCIDITY IN POULTRY MEATS BY THIOBARBITURIC ACID PROCEDURE

In 1960, Tarladgis, Watts and Younathan published an analytical procedure to determine the level of malonaldehyde in rancid foods by a distillation technique (J.A.O.C.S. 37, 44, 1960). Their method of procedure was somewhat modified by John H. Mahon (Hagen Chemicals & Controls, Inc.) and as such, was tried and adopted by the F.S.I. Analytical Laboratory. One minor change has been in our laboratory to improve the distillation technique resulting in a higher recovery of the malonaldehyde, and at the same time, effectively

controlling the foaming phenomenon. The addition of 20 grams of salt (NaCl) to the distillation flask proved to accomplish this.

PROCEDURE

1. Place 5,000 gram of a well ground meat sample in a 300 ml distillation flask. Add 100 ml of dilute HCl solution and a magnetic stirring rod. Stir to disperse the sample and assemble apparatus with a pre heated electric element.
2. Rapidly distil until exactly 50 ml of the distillate is collected (which requires approximately 6 minutes).
3. Mix the distillate and pipette a 5 ml aliquot into a 25 ml volumetric flask. Add 5 ml of T.B.A. reagent, stoppered the flask, mix the contents and immerse in a boiling water bath for 35 minutes.
4. Cool in tap water for 10 minutes and read the absorbance at 532 mu (Bausch & Lomb, Spectronic "20").
5. Multiply the absorbance by 11.6 factor and express as ppm of malonaldehyde.

REAGENTS

- T.B.A.: 0.02 M 2-thiobarbituric acid in 90% glacial acetic acid. Bring into solution by warming slightly.
- Dilute HCl Solution: Dissolve 200 grams of NaCl (Salt) in distilled water. Add 25 ml of 2 N HCl and make up a liter volume. Take 100 ml for test.
- Standard T.E.P.: 1 ml of T.E.P. (1,1,3,3-tetraethoxypropane) weights, $8961 \text{ g} \times 72/218 = 0.2960 \text{ g}$ of malonaldehyde. Dilute 20,000 times so that 1 ml will contain 0.0148 mgs.

What we claim is:

1. A process for the manufacture of dehydrated food-stuffs, feedstuffs, or plant fertilizers comprising the steps of:
 - (a) subjecting raw or uncooked, or substantially raw or uncooked, protein-containing animal matter to ultra homogenization, prior to the application of heat, to yield an average particulate size of less than about three microns and to reduce any tendons, skin or connective tissues to blend with muscle tissues and to break down fibrous tissue and emulsify associated fats resulting in a smooth, creamy, liquid to semi-solid homogenate;
 - (b) heating the resulting homogenate to form a protein agglomerate to effect gelation of said protein;

- (c) granulating the resulting agglomerate;
- (d) partially drying the granulated agglomerate;
- (e) kibbling the resultant partially dried and granulated agglomerate to break open case hardened protein film formed in step (d); and
- (f) drying the resultant Kibbles.
2. The process of claim 1 wherein the heat agglomeration of the protein achieved in step (b) is within a temperature ranging from about 50° to about 85° C.
3. The process of claim 1 wherein the granules are partially dried at a temperature not greater than 95° C.
4. The process of claim 1 wherein the granules are partially dried to a moisture content within the range of about 20% to about 50% by weight.
5. The process of claim 1 wherein the kibbles are dried to a moisture content of not more than 8%.
6. The process in accordance with claim 1, including the additional step of grinding the dried kibbles.
7. A process for the manufacture of a dehydrated protein-containing product comprising the following steps in order:
 - (a) subjecting proteinaceous animal matter to ultra homogenization prior to the application of heat, to yield an average particulate size of less than about 3 microns and to reduce any tendons, skin or connective tissues to blend with muscle tissues and to break down fibrous tissue and emulsify associated fats resulting in a smooth, creamy, liquid to semi-solid homogenate;
 - (b) heating the resultant homogenate to a temperature of between about 50° C. and 85° C. to agglomerate the protein in the homogenate to effect gelation of said protein;
 - (c) granulating the resultant agglomerate;
 - (d) partially drying the resultant granules at a temperature not greater than about 95° C. until their moisture content is within the range of about 20% to about 50% by weight;
 - (e) kibbling the resultant partially dried granules to break open case hardened protein film formed in step (d); and
 - (f) drying the resultant kibbles to achieve a moisture content not more than about 8% by weight.
8. The process as recited in claim 7, further comprising the additional step of grinding the dried kibbles.

* * * * *

EXHIBIT G

[54] DEVICES, COMPOSITIONS AND THE LIKE HAVING OR CONTAINING AN INORGANIC PYROPHOSPHATE

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[52] U.S. Cl. 424/49; 424/53;

424/57; 424/442; 426/549; 426/551; 426/805

[58] Field of Search 424/442, 49, 53, 57; 426/89, 94, 302, 289, 549, 551, 560, 805

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Primary Examiner—Ronald W. Griffin

[57] ABSTRACT

Devices, compositions and the like which have or contain at least one inorganic pyrophosphate salt. The devices or compositions are used to reduce or prevent tartar accumulations on dog teeth.

5 Claims, No Drawings

DEVICES, COMPOSITIONS AND THE LIKE HAVING OR CONTAINING AN INORGANIC PYROPHOSPHATE

BACKGROUND OF THE ART

1. Field Of The Invention

The invention relates to devices, compositions and the like having or containing an anti-tartar agent. The invention further relates to processes of preventing or reducing tartar formation on dogs' teeth by means of such devices, compositions and the like.

2. Background Art

Dental calculus, or tartar as it is sometimes called, is a deposit which forms on the surfaces of the teeth at the gingival margin. Supragingival calculus appears principally in the areas near the orifices of the salivary ducts; e.g., on the lingual surfaces of the lower anterior teeth and on the buccal surfaces of the upper first and second molars, and on the distal surfaces of the posterior molars. Mature calculus consists of an inorganic portion which is largely calcium phosphate arranged in a hydroxylapatite crystal lattice structure similar to one, enamel and dentine. An organic portion is also present and consists of desquamated epithelial cells, leukocytes, salivary desinent, food debris and various types of microorganisms. As the mature calculus develops, it becomes visibly white or yellowish in color unless stained or discolored by some extraneous agency. In addition to being unsightly and undesirable from an aesthetic standpoint, the mature calculus deposits are constant sources of irritation of the gingiva and thereby are a contributing factor to gingivitis and other diseases of the supporting structures of the teeth, the irritation decreasing the resistance of tissues to endogeneous and exogenous organisms.

A wide variety of chemical and biological agents have been suggested in the art to retard calculus formation or to remove calculus after it is formed in humans. Mechanical removal of this material is done routinely in humans.

German Patent No. 3,426,203 discloses a chewing article for dogs consisting of 92 volume parts of raw skin, 4 volume parts of lime and 4 volume parts of feed salts mixture containing (per 100 g) 700 mg of potassium, 1500 mg of carbonate, 1000 mg of calcium, 110 mg of phosphate, 40 mg of iron and 1 mg of iodine. The article is prepared from cow skin by stripping the skin, and subjecting the subcutaneous material to neutralization to pH 6, treating with a solution of iodine-containing feed salt and lime, shaping to form the article and drying.

U. S. Pat. No. 4,145,447 discloses a hard, unit-integral, unitized, self-contained, compact, chew-resistant nutritionally balanced animal food product 3 final having a density of at least about 0.5 oz./in³, a final water content of at least about 5.5 percent by weight, and a breaking force of at least about 60 psi. The animal food contains, for example, dried meals, dried fish, dried dairy products, fish meal, fish flour, cereals, flours carbohydrates, dried fruits, etc., with or without food additives or supplements such as vitamins, minerals, medicinal, etc., for example chemicals, enzymes, etc., capable of removing plaque or tartar from the animals' teeth, etc.

U. S. Pat. No. 4,044,158 discloses the use of tetrasodium pyrophosphate as a chelating agent in semi-moist pet foods. The neutral chelating agent is used in a semi-

moist pet food having a pH of from 6.3 to 7.2 and which comprises about 5 to about 50 percent by weight meat or meat by-products, about 15 to about 50 percent moisture, and about 1 percent to about 26 percent by weight vegetable protein. The vegetable protein, an amylaceous material, and the chelating agent, it is taught, forms a composition which replaces part of the caseinate binder customarily present in a semi-moist pet food. No mention is made of any anti-tartar effectiveness of the pet food.

U. S. Pat. No. 4,215,149 discloses a process for maintaining the palatability of a pet food by coating particulates having a moisture content of less than 15 percent with fat and then with a monovalent metal or monovalent earth metal salt of phosphoric acid to make the food more palatable to cats. Exemplary salts are monosodium phosphate and monocalcium phosphate.

U. S. Pat. No. 3,639,569 discloses the use of a tris-(phosphonoalkyl)amine in a dentifrice composition with a dentifrice abrasive selected from the group consisting of beta-phase calcium pyrophosphate, particulate thermosetting polymerized resin, alumina, sodium metaphosphate, and mixture thereof, or in a mouthwash composition, or in a chewing gum composition or dental prophylaxis paste composition. The patent discloses that the use of inorganic pyrophosphates as anti-calculus agents in oral compositions has the problem of hydrolysis in aqueous products and loss of activity prior to the termination of the normal shelf-life of such products. The patent also teaches that calculus inhibition by chelation of calcium ion may seriously damage tooth structure by decalcification.

U. S. Pat. No. 3,957,964 discloses microcapsules containing essential oils of mint flavor in a dentifrice adapted to release a plural flavor-burst signaling the onset of and the completion of a toothbrushing operation. The dentifrice may be a toothpaste having dicalcium phosphate as a polishing agent.

U. S. Pat. No. 3,959,458 discloses the use of from about 0.2 to about 8 percent by weight of an orally acceptable monofluorophosphate with an anticalculus agent which is a condensation product of ammonia and phosphorus pentoxide or with a polyphosphonate in an oral composition. The oral composition may further contain a calcium pyrophosphate abrasive. The patent teaches that sodium or 4 Calcium monofluorophosphate, when used in combination with the anticalculus agents, exhibit no detectable damage to silicate fillings in the mouth whereas other anticaries agents, such as sodium fluoride, do exhibit damage. It is also taught that below about pH 5.0 some of the anticalculus agents can damage dental enamel.

U. S. Pat. No. 4,314,990 discloses the use of a phosphate buffering agent, which provides phosphate ions to maintain the pH of a slurry in the range of about 6.8 to 8.0, in a toothpaste composition which comprises 6 to 45 percent of a silica dental abrasive, from about 0.01 to 3 percent of a fluoride ion source, from about 10 to 45 percent of water, and about 30 to 70 percent of humectant.

U. S. Pat. No. 4,323,551 discloses the use of a tetraalkali metal pyrophosphate salt to provide from about 0.5 to 5 percent of the P₂O₇ species in a mouthwash composition comprising 0.02 to 0.2 percent of a quaternary ammonium compound, and a carrier liquid wherein the pH is adjusted to about 7.0 to 9.5 with a mineral or organic acid.

U. S. Pat. No. 4,421,527 discloses the use of a precipitated amorphous silicon dioxide prepared by acidulation in an abrasive composition in a toothpaste that contains fluoride. Phosphoric acid is disclosed as an acidulant. Soluble phosphates, such as the pyrophosphates, are taught as improving fluoride pellicle penetration.

U. S. Pat. No. 4,515,770 discloses a process wherein a soluble source of phosphate ions or a soluble source of calcium ions is uniformly distributed through sucrose in crystalline form as a result of dissolution of the sucrose and soluble source of calcium or phosphate ions in water followed by evaporation of the water solvent. It is taught that it is of substantial importance that the calcium or phosphate ion source be as rapidly soluble in saliva as the sugar so that the protective ions will migrate to salivary retention areas as rapidly as the sugar. A material, it is taught, which is cariogenic by virtue of directly or indirectly participating in the lowering of pH in salivary retention areas is rendered non-cariogenic by treatment to incorporate enough of either a calcium or phosphate ion source to keep the acidic medium from dissolving the tooth enamel. It is also disclosed that systematically administered phosphates are said to differ in cariostatic activity depending on the type of anion (cyclical, trimeta-, hexameta-, ortho-, and pyrophosphate, increasing in effectiveness in that order). It is further taught that these developments have unfortunately resulted in only minor advances in prevention of carious degradation of teeth because none of the "remineralization" processes have been shown to be consistently effective.

U. S. Pat. No. 4,515,772 discloses the use of from about 10 to about 70 percent of a dental abrasive selected from the group consisting of insoluble metaphosphates, alumina, thermosetting polymerized resins, and silica from about 50 to about 3,500 ppm of fluoride ions from a fluoride ion source, and an amount of a pyrophosphate salt selected from the group consisting of dialkali metal and mixtures of dialkali metal and tetraalkali metal pyrophosphate salts sufficient to provide at least 1.5 percent P_2O_7 . The pyrophosphate ion is provided by a P_2O_7 mixture of disodium pyrophosphate and tetrasodium pyrophosphate. The fluoride ion source is disclosed as an essential component. The upper limits on the sodium pyrophosphate salts are determined by solubility considerations, while the tetrapotassium level is established for taste reasons. It is further taught that surprisingly mixtures of certain pyrophosphate salts can provide a safe and effective anti-calculus product while also not presenting difficult formulation problems.

U. S. Pat. No. 4,532,124 discloses the use of a plaque mineralizing aqueous solution comprising urea, a fluoride salt, a water-soluble calcium salt, and a water-soluble phosphate salt in the mineralization of dental plaque. It is disclosed that high plaque calcium and inorganic phosphate levels will lower the critical pH, that is, the pH which plaque must reach before it becomes unsaturated with respect to biological apatite, and enamel dissolution commences. The urea is metabolized by bacteria to produce alkali in plaque. Aspartame and amino acids may be substituted for the urea.

U. S. Pat. No. 4,540,584 discloses the use of coral sand as an effective component in a mineral supplement in an amount sufficient to provide calcium carbonate as a mineral supplemental for humans, such coral sand also containing PO_4 . The composition, is useful for replen-

ishing calcium and phosphorous, as well as other minerals. Acidic foods tend to result in decayed teeth and bone fractures because of calcium poverty.

U. S. Pat. No. 3,567,459 discloses conversion of a hot melt of sugar having a moisture content less than 5 percent to a dough-like bone-forming composition by incorporation of nutritional fillers, fatty flavoring materials, and fat-absorbing farinaceous materials. The composition is formed and cooled. The patent teaches mastication of bones provides teeth cleaning benefits stemming from abrasion and other contacts of bone fragments.

U. S. Pat. No. 3,701,830 discloses the use of a neutral protease enzyme for removing plaque from and preventing the formation of calculus on the teeth of dogs wherein the neutral protease is obtained by fermentation with a strain of *Bacillus subtilis* or *Bacillus stercorophilus*.

U. S. Pat. No. 3,882,257 discloses a process where 75 percent by weight of bones is admixed with 23.5 percent by weight of animal by-products, and the mixture is bound with salt in the preparation of a pet food having about 40 percent natural animal protein. The product enables a dog to exercise his jaws and gums to remove tartar from teeth.

U. S. Pat. No. 3,899,607 discloses a dough mixture which is worked and shaped at a temperature of 170° to 220° F to form a simulated bone having a structural matrix; or cooked, dried to a moisture content of between 5 and 12 percent by weight, ground and mixed with a dextrin adhesive to form a simulated bone having a structural matrix.

U. S. Pat. No. 4,364,925 discloses that an enzyme for removing plaque and/or tartar from the teeth is included in a chew-resistant layer of an integral chew-resistant multi-layer animal food system having a structure supporting fibers. U. S. Pat. Nos. 3,194,738 and 3,686,393 also relate to the use of enzymes for inhibiting plaque.

U. S. Pat. No. 3,488,419 discloses the use of a polyphosphonate or salt thereof in compositions like dentrifices, mouthwashes, prophylaxis pastes and topical solutions. The patent teaches that inorganic polyphosphates, such as pyrophosphates, hydrolyze in aqueous products and do not remain in active form throughout the normal shelf-life of such products. Calculus and crystal growth inhibition tests on rats using calculus prophylaxis are disclosed. The patent also teaches that calculus inhibition by chelation of calcium ion may seriously damage tooth structure by decalcification.

U. S. Pat. No. 3,535,420 discloses the use of a cyclic tetraphosphonic acid as a anti-calculus agent in an oral composition. The patent teaches that inorganic polyphosphates, such as pyrophosphates, hydrolyze in aqueous products and do not remain in active form throughout the normal shelf-life of such products. It is also taught that although certain of the art-disclosed chelators are purportedly safe for use on dental enamel, the chemical similarity of calculus to the tooth structure limits the usefulness of the chelation approach because the more effective chelators can seriously damage the tooth structure by decalcification. The cyclic tetraphosphonates are calcium sequestrants, but they retard calculus formation by a mechanism that is believed to involve the inhibition of hydroxylapatite crystal growth rather than calcium sequestering.

U. S. Pat. No. 3,686,393 discloses the use of a dextranase used to eliminate dental plaque formation.

U. S. Pat. No. 3,956,479 discloses the use of a quaternary ammonium compound having a carbamate, or a thiocarbamate, or a dithiocarbamate, or a carbamide group in an oral preparation. The compounds are effective in reducing caries and inhibiting formation of oral calculus.

U. S. Pat. No. 4,003,971 discloses the use of a dentifrice component in the production of dentifrice speckles. Antimicrobial agents for incorporation into oral dentifrice formations may be effective by reducing dental plaque or inhibiting the formation of dental calculus.

U. S. Pat. No. 4,254,101 discloses the use of from about 6 to 45 percent of a silica dental abrasive, from about 30 to 70 percent of a humectant, and from about 0.03 to 1.0 percent of a carboxyvinyl polymer in a toothpaste composition. The use of optional anticalculus agents in amount of from about 0.01 to 2.5 percent by weight of the toothpaste composition are taught.

U. S. Pat. No. 4,472,373 discloses the use of a pyridium salt as an anti-plaque agent in a flavored alcoholic carrier. Phosphates, such as calcium pyrophosphate, are disclosed as dentifrice abrasives.

U. S. Pat. No. 4,153,732 discloses the use of at least one soluble aluminum ion containing salt with adipic acid, ascorbic acid, or mixtures thereof as a cariostatic additive for comestibles. The patent teaches that calcium pyrophosphate and insoluble sodium metaphosphate abrasives coact with aluminum fluoride in dentifrice compositions.

U. S. Pat. No. 4,627,977 discloses an oral composition, such as, a toothpaste (including gel or cream), mouthwash, lozenge, chewing gum or tooth powder, containing a calculus-inhibiting amount of a linear molecularly dehydrated polyphosphate salt (e.g., a water-soluble alkali metal pyrophosphate) to inhibit enzymatic hydrolysis of said polyphosphate salt in saliva, a combination of a fluoride ion-providing source and a synthetic linear polymeric polycarboxylate. See also British Published Patent Application No. 2,180,157.

U. S. Pat. No. 4,678,662 discloses calcium carbonate particles coated with at least one pyrophosphate derivative, such as, sodium dihydrogen pyrophosphate and tetrasodium pyrophosphate.

European Published Patent Application No. 0236920 discloses a dentifrice comprising essentially insoluble calcium pyrophosphate as an abrasive and a clinically effective amount of soluble pyrophosphate, such as, tetrasodium pyrophosphate, or tripolyphosphate as an anticalculus agent.

U. S. Pat. No. 4,684,518 discloses a process for reducing the incidence of calculus on dental enamel. The enamel surfaces in the mouth are contacted with a composition comprising a soluble pyrophosphate source capable of providing at least 1.5 percent of P_2O_7 and from about 50 to about 3500 ppm of fluoride.

U. S. Pat. No. 4,722,461 discloses an oral composition in the form of a mouthwash or liquid dentifrice comprising: an amount of a fluoride ion source sufficient to supply from about 50 ppm to about 3500 ppm of fluoride ions; an amount of a pyrophosphate salt selected from the group consisting of dialkali metal and mixtures of dialkali metal and tetra-alkali metal pyrophosphate salts sufficient to provide at least 1.5 percent of P_2O_7 ; and water. The pH of the composition is percent of P_2O_7 and water. The pH of the composition 1 from about 6.0 to about 10.0. Calcium pyrophosphate is termed to be an abrasive. See European Published Patent Application No. 0097476.

British Published Patent Application No. 2,201,593 discloses an oral composition in the form of a toothpaste effective in reducing calculus comprising: a safe and effective amount of a soluble pyrophosphate salt or mixture of the salts; from about 5 to about 60 percent of a suitable toothpaste abrasive; an amount of a fluoride ion source sufficient to provide from about 50 ppm to about 3500 ppm fluoride; from about 5 to about 60 percent of humectant selected from the group consisting of sorbitol, glycerine, polyethylene glycols, mineral oil, and mixtures thereof; from about 0.3 to about 5 percent of a surfactant selected from the group consisting of alkyl sulfate surfactants, ethoxylated alkyl sulfate surfactants and mixtures thereof; and water. The composition has a pH of from about 6 to about 10, is substantially free of polyethylene glycols having fewer than six ethoxy units and short chain monohydric alcohols and has potassium ions present at a level of from about 0.5 to about 7 percent. The soluble pyrophosphate salt can be, for example tetrapotassium pyrophosphate, tetrasodium pyrophosphate, sodium acid pyrophosphate and mixtures thereof.

U. S. Pat. No. 4,806,340 discloses an oral dentifrice composition such as a toothpaste, dental gel, toothpowder, dental tablet or lozenge containing as anticalculus agent about 4.3 to about 7 percent of alkali metal pyrophosphates comprising at least 4.3 percent of tetrapotassium pyrophosphate alone or admixed with up to 2.7 percent of tetrasodium pyrophosphate, and as inhibitors against enzymatic hydrolysis of such agent in saliva, a fluoride and preferably up to about 3 percent of a synthetic anionic polymeric polycarboxylate. The composition is used in a program of oral hygiene and/or for inhibiting dental calculus. It is known that saliva contains acid phosphatase, alkaline phosphatase and pyrophosphatase enzymes. It is considered that any one of the three enzymes may adversely affect pyrophosphates as an inhibitor of hydroxyapatite formation and calculus. It is accordingly apparent that an anticalculus pyrophosphate dentifrice composition, should inhibit, reduce or nullify the destructive activity of all three salivary enzymes. See also British Published Patent Application No. 2,182,244.

Australian Published Patent Application No. 168071 discloses a dialkali metal-alkaline earth metal pyrophosphate containing about 1 to about 5 percent by weight of chemically combined fluoride. The composition is a dentifrice base. The method of producing the fluorinated dialkali metal-alkaline earth metal pyrophosphate, which comprises reacting together, in the presence of an aqueous medium, a water-soluble metal fluoride, an alkali metal pyrophosphate (such as, tetrasodium pyrophosphate), and a water soluble alkaline earth metal salt. The reactants being employed in the proportions required to yield a dialkali metal-alkaline earth metal pyrophosphate containing about 1 to about 5 percent by weight of chemically combined fluoride.

British Patent No. 777,556 discloses a dentifrice composition which contains a fluoride compound which releases fluoride ions in water, a calcium polyphosphate polishing agent, and a calcium ion suppression agent to maintain the effect of the fluoride upon aging.

U. S. Pat. No. 4,822,626 discloses a process of producing a biscuit with a baked-on proteinaceous coating. The process includes preparing a dough piece from a dough comprising flour, meal, fat and water; and enrobing the dough piece with a viscous coating formation comprising 10 to 30 weight percent of a dextrin carrier,

10 to 50 weight percent of meat, 10 to 30 weight percent of a glazing agent, 1 to 5 weight percent of polysaccharide gum, 5 to 15 weight percent of a monosaccharide sugar, 5 to 15 weight percent of a disaccharide sugar, and water, all based upon the total dry solids. The dough piece is baked to form a dry biscuit with a baked-on coating. The glazing agent can comprise a gelatin or a modified food starch, and the polysaccharide gum can be a xanthan gum. Biscuits produced by the process and a bakable proteinaceous coating formulation as employed in step (b) are disclosed.

BROAD DESCRIPTION OF THE INVENTION

An object of the invention is to provide devices, compositions and the like containing pyrophosphate. A further object of the invention is to provide processes for the prevention or reduction of tartar accumulation on the teeth of dogs by such devices, compositions and the like. Other objects and advantages of the invention are set out herein or are obvious herefrom to one skilled in the art.

The objects and advantages of the invention are achieved by the compositions and processes of the invention.

Tartar is an incrustation of the teeth consisting of salivary secretion, food residue and various salts, such as, calcium carbonate or phosphate. Tartar is also termed dental calculus.

Caries are cavities or decay of the teeth which begins at the surface of the tooth and may progress through the dentine into the pulp cavity. It is believed that the action of microorganisms in the mouth on ingested sugars and carbohydrates produces acids that eat away the enamel. By preventing the formation of calculus or tartar, the invention formulation is in effect an anti-cariogenic agent.

The invention involves an animal or dog food, such as, a dog biscuit, having a soft, edible center which contains at least one inorganic pyrophosphate. The center is made soft by the inclusion of a softening agent, such as, at least one humectant. The preferred humectant is propylene glycol. The animal food reduces or prevents the accumulation of tartar on the animal's teeth.

The invention also involves animal foods, such as, dog foods, having a coating containing at least an inorganic pyrophosphate. The coated animal food reduces or prevents the accumulation of tartar on the animal's teeth.

The invention also involves swabs, gauze and other like materials having absorbed/adsorbed therein and/or thereon a solution containing at least one inorganic pyrophosphate. The treated swab or treated gauze reduces or prevents the accumulation of tartar on the animal's teeth.

The invention further involves swabs, gauze or other like materials having thereon and/or therein a coating containing at least one inorganic pyrophosphate. The coated swab or coated gauze reduces or prevents the accumulation of tartar on the animal's teeth.

The invention involves meat jerky, such as, beef jerky, having absorbed/adsorbed therein and/or thereon a solution containing at least one inorganic pyrophosphate. The treated meat jerky reduces or prevents the accumulation of tartar on the animal's teeth.

The invention involves meat jerky, such as, beef jerky, having a coating therein and/or thereon a coating containing at least one inorganic pyrophosphate. The

treated meat jerky reduces or prevents or reduces the accumulation of tartar on the animal's teeth.

The invention still further involves a process of preventing or reducing tartar accumulation on the teeth of an animal, comprising:

(a) spraying an aqueous solution containing at least one inorganic pyrophosphate onto an animal food; and

(b) having an animal consume the treated animal food.

The invention deals primarily with dogs, but has a scope of teeth bearing non-human mammals and other animals, such as, cats and dogs.

DETAILED DESCRIPTION OF THE INVENTION

As used herein, all parts, percentages, ratios and proportions are on a weight basis unless otherwise stated herein or otherwise obvious herefrom to one skilled in the art. As used herein, all temperatures are in degrees Fahrenheit unless otherwise stated herein or otherwise obvious herefrom to one skilled in the art.

The invention involves a dog food, such as, dog biscuits, having a soft center containing at least one inorganic pyrophosphate. The center is softer than the rest of the dog biscuit, which can be a soft or hard dog biscuit. The center is made soft by the inclusion of at least one softening agent, such as, at least one humectant.

The outer portion of the dog food, such as, dog biscuits, can be made from any suitable dog food dough, such as, suitable dog biscuit dough. Any suitable dough comprising at least one flour, meal, fat and water can be employed for the product. For instance, when the desired product is a canine biscuit, a conventional dough for dog biscuits can be used, optionally containing discrete particles of meat and/or meat byproducts or farinaceous material. Such doughs typically contain fat solids. Examples of suitable doughs for the production of hard dog biscuits are disclosed in U. S. Pat. No. 4,454,163, and suitable doughs for the production of soft dog biscuits (containing humectant to control water activity) are disclosed in U. S. Pat. No. 4,454,164. The pertinent portions of U. S. Pat. Nos. 4,454,163 and 4,454,164 are incorporated herein by reference. Particulate proteinaceous particles, such as particles of meat, texturized vegetable protein and/or meat byproducts can be incorporated to add flavor to the biscuits and texturize the surface. Particulate farinaceous materials such as bran particles can also be employed to texturize the interior and/or surface of the biscuits and to provide other useful properties to the product. A dough found to produce biscuits highly palatable to dogs includes suitable proportions of wheat flour, wheat meal, soybean meal, meat and bone meal, animal fat and natural flavors in admixture with water. The meal used in the doughs suitable for production of biscuits useful in the invention can comprise meat and/or bone and/or vegetable matter including farinaceous materials, materials prepared from legumes such as beans and peas, tuberous materials such as potato meal, and the like. The means can be finely or coarsely ground as desired for the texture. Flours made from any suitable farinaceous material can be used.

The doughs generally have a water activity of about 0.90 and above upon completion of mixing of the dough ingredients. A suitable dough contains farinaceous material, an edible oil, an antioxidant, an antimicrobial, salt,

animal fat, added vitamins and minerals, such as those disclosed in U.S. Pat. No. 4,229,485, column 5, lines 7 to 57, which is incorporated herein by reference. The compositions of the invention also preferably contain at least one animal-derived proteinaceous meal such as meat meal, bone meal and fish meal. A good biscuit dough for producing the biscuits of the invention contains about 50 to 60 percent by weight wheat flour, about 5 to 10 percent by weight soybean meal, about 3 to 10 percent by weight meat and bone meal, about 1 to 5 percent wheat meal, about 1 to 5 percent animal fat preserved with BHA, about 20 to 30 percent by weight water, and about 2 to 5 percent by weight of natural flavors, vitamin and mineral preblend, and acidulant.

The soft center portion of the dog biscuit contains a softening agent if it is made from a dog biscuit dough. Any suitable softening agent can be used. The preferred humectant is propylene glycol. Examples of other suitable humectants are corn syrup, sugar and polyalcohols, such as, sorbitol and glycerin. Any suitable humectant known in the art can be used.

If the softening agent is used in the outer portion of the dog biscuit, more of a softening agent should be used in the central portion to make it softer than the outer portion.

The solvent used in preparing the dog biscuit dough for the center portion is most preferably water, but other non-toxic, edible solvents, such as, ethanol or ethanol/water, can be used. The problem of the necessity of solvent removal from the dough due to toxicity is to be avoided. If a mixture of ethanol and water is used, the amount of ethanol in the mixture is generally about 5 to 60 percent, preferably about 5 to about 25 percent. When one or more of the inorganic pyrophosphates is not water soluble, it may be ethanol soluble. It may be necessary to use a non-aqueous solvent, or mixture of water therewith, to incorporate the inorganic pyrophosphate.

The invention includes the use of at least one inorganic pyrophosphate. Preferably the inorganic pyrophosphate(s) is water soluble. A mixture of pyrophosphates can be used to provide a desired pH. Water-insoluble or difficultly soluble inorganic pyrophosphates can be used.

The pH of the dough can be adjusted using an inorganic base (e.g., KOH, NaOH, CaOH, LiOH, MgOH, etc.) or an inorganic base (e.g., H₂SO₄, HCl, etc.), but this approach has the disadvantages of possibly causing a misbalance or overabundance of one or more chemical entities and possibly introducing unwanted salts.

Generally 0.1 to 10 weight percent, preferably about 0.5 to about 3.5 weight percent and most preferably about 1.4 to about 2.5 weight percent of inorganic pyrophosphate is used.

When a mixture of tetrasodium pyrophosphate (TSPP) and sodium acid pyrophosphate in aqueous solution at the 5 weight percent level was incorporated in dog biscuit dough, there was reduced dough gluten development, the dog biscuits were bleached (whitish) and crumbly, and the dog biscuits were softer (a hardness problem) than the control dog biscuits. At the level of 3 weight percent of a mixture of tetrasodium pyrophosphate and sodium acid pyrophosphate, the same problems occurred, but less severely. The addition of the inorganic pyrophosphates in dry form to the dry ingredients in the dough preparation basically eliminated the above problems. It was also found that better

results were secured by using the inorganic phosphates in powder form as opposed to granular form.

The inorganic pyrophosphates are preferably alkali metal pyrophosphates. The preferred alkali metal pyrophosphates are tetrasodium pyrophosphate and tetrapotassium pyrophosphate. An example of a useful tetraalkali metal pyrophosphate is tetralithium pyrophosphate. Alkaline earth metal pyrophosphates are also useful, but they are generally insoluble in water. Preferably, the inorganic pyrophosphates are soluble in water.

Examples of dialkalin metal pyrophosphates are dicalcium pyrophosphate, dibarium pyrophosphate and dimagnesium pyrophosphate. Trialkali metal monosodium pyrophosphates, such as, trisodium hydrogen pyrophosphate, can be used. Monoalkali metal triacid pyrophosphates, such as, disodium trihydrogen pyrophosphate, can also be present in limited amounts. Examples of other inorganic pyrophosphates include manganese pyrophosphate and dizinc pyrophosphate.

Tetrasodium pyrophosphate, one part, is soluble in 13 parts of cold water and in 2.5 parts of boiling water. It is insoluble in ethanol. Dicalcium pyrophosphate is practically insoluble in water. The invention use of the term "solution" includes slurries, suspensions and the like. Tetrapotassium pyrophosphate is freely soluble in water and is insoluble in ethanol.

Most preferably a mixture of sodium acid pyrophosphate and tetrapotassium pyrophosphate is used (in a ratio to achieve the desired pH).

The maximum allowable GRAS level in a composition for sodium acid pyrophosphate (SAPP) is 2.1 weight percent and tetrapotassium pyrophosphate (TKPP) is 1.4 weight percent in baked goods. If GRAS levels change (rise) or if higher levels are allowed by the regulatory agencies, higher levels can be used in the invention. TKPP delivers approximately 52.65 percent of P₂O₇; SAPP delivers about 78.36 percent of P₂O₇; and TSPP delivers about 65.4 percent of P₂O₇.

The most preferred invention dough contains trisodium monosodium pyrophosphate (that is, sodium acid pyrophosphate or SAPP) and tetrapotassium pyrophosphate in a weight ratio of about 60 to 40.

The pyrophosphate(s) is used in sufficient amount to deliver generally from about 0.1 to about 5, preferably from about 0.5 to about 3.5, most preferably 1.4 to 2.5 weight percent (based on the total composition), of P₂O₇.

A study of the application of aqueous solutions of a mixture of tetrasodium pyrophosphate and sodium acid pyrophosphate to the teeth of dogs by spraying for one month resulted in dose response data. The aqueous solutions containing 5 and 3 weight percent of a mixture tetrasodium pyrophosphate and sodium acid pyrophosphate resulted in significant reductions in tartar accumulation. The aqueous solutions containing 1.5 and 0.5 weight percent of a mixture of sodium acid pyrophosphate and tetrasodium pyrophosphate resulted in directional trends of reductions in tartar accumulation. See also U.S. Pat. No. 3,323,551.

The ratio of sodium acid pyrophosphate (SAPP) to tetrapotassium pyrophosphate (TKPP) is generally between 4 to 1 and 3 to 7, preferably between 7 to 3 and 1 to 1, most preferably about 3 to about 2. SAPP has a pH of 4.2 and TKPP (and TSPP) has a pH of 10.2, so the combination of SAPP and TKPP (or TSPP) provides a resultant pH which is a balance of the pHs of the two components.

The pH of the dough of the inner portion containing at least one inorganic pyrophosphate compound (salt) is generally in the range of about 4 to about 10.5, typically from about 4.5 to about 7.5, preferably from about 5 to about 7, most preferably between about 5.6 and about 6.1. Milk Bone® dog biscuit has a pH of 6.1 to 6.4. Tartar reduction is indicated to be best at a neutral pH and palatability is indicated to be best at a slightly acidic pH, so the best mode contemplates a balance of such two factors in any commercial product.

The dough ingredients are generally mixed at a temperature of about 45° to about 140° F., preferably about 60° to about 125° F.

The dog biscuit dough for the outer portion and the inner portion can be mixed using any suitable or conventional equipment. For example, the mixing can be at 20 to 100 rpm. For example, a dry blending step (dries and the inorganic pyrophosphates) can be done typically at room temperature for a period of time of about 3 minutes to about 20 minutes. The dry-blended mixture can then be mixed with the hot water to form a first stage dough. The water which can be admixed with the dry-blended mixture is typically at a temperature of about 65° to about 150° F. The hot water can be added, with mixing, over a period of time of about 3 minutes to about 6 minutes to form the first stage dough. Then, the fat portion of the biscuit dough can be admixed with the first stage dough to form the final stage dough. The fat portion can be added at a temperature at which it is at least fluid, typically at about 100° to about 150° F. The fat portion can be mixed for a period of time which is sufficient to form a dough whose homogeneity is visually apparent. A typically final mixing time is about 3 to about 5 minutes.

If there are machinability and dough structure property problems with the center portion dough, the addition of water should solve such problems. If the use of the higher water levels caused the dough to be so sticky as to cause problems in a sigma or rotary mixer (but normally not a significant problem in a continuous mixer). The addition of more tallow to the dog biscuit dough should assist in more effective mixing and help to keep the dough from being so sticky that it clings to a rotary molder. Preferably the tallow level is about 2.6 to about 3.1 weight percent (most preferably about 2.85 weight percent), as opposed to a tallow level of about 2.46 weight percent in Milk Bone® dog biscuits. Also, the tallow provides a taste which dogs like.

Formation of the dough is achieved at about atmospheric pressure with mixing of the components being conveniently achieved in an upright sigma blade mixer or other bakery-type mixers. The various ingredients can be added over a period of time or in a one-shot manner according to the above order of addition. However, melted fat and water can be added simultaneously and mixed for 6 to 10 minutes.

The center portion of the dog biscuit can also be a fruit filler, e.g., a fruit gel composition, containing at least one inorganic pyrophosphate.

The dog food composition, such as, dog biscuits, having a soft center portion can be prepared by any suitable method, such as, convention deposition of the center portion on a dough piece and then capped by another dough piece, the edges of such pieces preferably being pressed together. Such dough pieces can be formed in any suitable or conventional manner, such as, by extrusion, stamping, cutting or molding. Preferably the food composition is prepared by the coextrusion of

the outer portion and the soft center portion. Any suitable dog food composition shapes or dog biscuit shapes can be used, such as, bone-shaped canine biscuits. Holes can be formed in the dog food composition or dog biscuits to facilitate the escape of moisture during baking, cooking and/or drying.

The dog biscuit dough pieces can be baked using any suitable or conventional equipment and conditions. For example, the dog biscuit dough pieces can be passed into an oven such as a conventional band oven where the biscuits are baked. The conveyor belts of the oven can be coated with an edible lubricant such as a natural or synthetic cooking oil or shortening to facilitate separation from the conveyor belts of the baked products. Temperatures in the range of about 300° to about 600° F. can be used. The baked dog biscuits can also be subjected to subsequent drying at temperatures of about 200 to 400° F., either within the baking oven or separately, to produce the desired moisture content in the final product.

The formed dog biscuit dough pieces are baked, followed by drying, to achieve a shelf stable product without the need of any moisture barrier protection. Baking and drying temperatures and times are those conventionally used in the production of a dry canine biscuit. The pieces are dried to obtain a biscuit having a water activity of 0.70 or less. Typically, baking temperatures and times are about 300° F. to about an average of 475° for about 25 minutes to about 8 minutes. Drying conditions are typically about 200° to about 325° F. for about 25 minutes to about 12 minutes in a forced air dryer. On a weight basis, the moisture content of the final biscuit product is less than or equal to about 15 percent by weight and preferably about 10 to 12 percent by weight of the final biscuit at 70 percent relative humidity.

The invention product does not include any fluorine-containing compound or other fluoride ion source, or quaternary ammonium compounds. Also the invention product does not include any organic pyrophosphates.

The invention deals primarily with dogs, but has a scope of teeth-bearing non-human mammals, such as, cats.

The invention composition can be used to reduce and control tartar accumulation on canine teeth. Based upon the weight of commercial Milk Bone® dog biscuits: 12 small invention dog biscuits per day, 10 medium invention dog biscuits per day, 6 large invention dog biscuits per day or 4 extra large invention dog biscuits per day will supply about $\frac{1}{4}$ to $\frac{1}{2}$ of a dog's caloric requirement.

The invention also involves animal foods, such as, dog foods, having a coating containing at least one inorganic pyrophosphate. The above information regarding inorganic pyrophosphates also applies here; the coating can contain the same amounts and type of inorganic pyrophosphates as in the case of the soft center portion.

The coating is preferably applied to the animal food in the form of a liquefied coating formulation by any suitable means, such as, dipping, spraying, etc. The coating can encompass all or part of the animal food.

The liquefied coating formulation best contains at least one suspension agent. The preferred suspension agent is a polysaccharide gum, most preferably xanthan gum. Preferably about 0.05 to 1.75 weight percent of polysaccharide gum (xanthan gum) is used. Xanthan gum is one of the few gums which acts as an acceptable suspension agent in the invention. The xanthan gum is an excellent agent for controlling the bodying effect, as

it is stable over a broad temperature range, i.e., it holds the same viscosity over a large temperature range without any separation of the coating ingredients. The xanthan gum has a bodying effect so that little or no separation occurs. Other suitable gums and mucilages can be used.

Malto-dextrin produced by hydrolyzing corn starch is preferred; it serves as a carrier (bodying), binding agent and suspension agent and helps the appearance of the coating; and it is a preferred ingredient. Other malto-dextrins can also be used for the same functions.

An adhesive or binding agent, such as, malto-dextrins, is needed in the coating slurry to help the coating material bind (adhere) to the raw hide when the raw hide is dipped in the coating slurry. Preferably about 5 to about 15 weight percent of the malto-dextrin is included in the coating material.

A carrier, such as, starch or a modified food starch, is included in the coating formulation. Preferably about 0.1 to about 5 weight percent of the food starch or modified food starch is included in the coating material. The food starch or modified food starch also serves to control the viscosity.

Animal fat preferably is included for flavor purposes. Other suitable flavorants can be used or included, particularly salt. The flavorants can be any dairy product flavorant, such as milk or cheese, meat flavorants, such as, liver or beef, poultry and fish. Flavorants help provide palatability for the invention coating.

Preferably a hydrogenated vegetable oil is included in the coating formulation for sheen and to modify the melting point of the formula fats in the finished product. It also helps to prevent flaking of the coating; also the coating does not have a tacky feeling.

Any suitable colorant can be included in the coating formulation. The preferred colorant is caramel color which also provides some flavor to the product.

The coating also incorporates sufficient water to achieve the liquefied coating composition. Amounts of the other ingredients are those which are effective to achieve their functions in the coating formulation.

The preferred coating formulation, besides the inorganic pyrophosphates, contain animal fat, a surfactant, such as, a modified lecithin, polysaccharide gum, a modified food starch, flavorant, colorant, hydrogenated vegetable oil, a carrier, such as a malto-dextrin, and water. A suitable humectant, preferably propylene glycol, can be used in the coating formulation.

The coating formulation should be viscous enough so that the coating formulation generally only coats the surface regions of the animal food. The presence of coating in the surface regions of the animal food helps to anchor the resultant coating and to prevent the coating from easily being separated from the animal food during handling and shipping. Basically though the coating is strictly a surface phenomena on the animal food.

The coating slurry can be applied to the animal food by any suitable means, such as, spraying, dipping, soaking in a container, etc. The coating slurry is applied generally at a temperature of 45° to 200° F., preferably at about 60° to about 190° F., and most preferably at about 180° F. The coating slurry has a low microbial profile at such higher temperatures.

After treating the raw hide with the pyrophosphate slurry, the coated animal food is dried and/or baked. While the coated animal food is preferably air dried, it is also advantageous to dry the coated animal food using

applied heat, e.g., in a hot air oven (at a temperature of say 75° F. to 300° F.).

The preferred embodiment and ranges of the above type of coating is:

Ingredients	Percentages	
	Specific	Ranges
Sodium acid pyrophosphate (SAPP), anhydrous powder, (non-leavening type)	1.73	0.25-5
Tetrapotassium pyrophosphate (TKPP), anhydrous powder	1.15	0.25-5
Salt	0.50	0.05-2.50
Malto-dextrin	9.17	2-30
Food starch modified	2.00	0.1-10
Colorant	0.50	0.01-3
Flavorant	2.00	0.01-5
Xanthan	0.20	0.05-1.5
Lecithin or modified lecithin	1.25	0.5-1.75
Vegetable Fat	0.50	0.1-3
Animal Fat	1.00	0.1-5
Water	Subtotal	20.00
	Total	80.00
		50-about 97

The following coating-baking procedure is particularly advantageous:

- (a) dry blending the dry powder.
- (b) adding $\frac{1}{4}$ of the water and slurring the composition.
- (c) adding remaining $\frac{3}{4}$ of the water and mixing to form the coating formulation.
- (d) heating the coating formulation to 185° to 200° F. with intermittent stirring (add animal fat at about 125° F. during the heating).
- (e) maintaining the coating formulation at 160° to 190° F.
- (f) apply the coating material to the unbaked dough pieces.
- (g) baking the coated, unbaked dough pieces at 325° F. for 25 minutes.
- (h) drying the baked, coated dough pieces for 25 minutes at 225° F. in a forced-air dryer.

The animal food within the scope of this invention needs to have a sufficient integrity to not fall apart during processing and handling, especially, so that the coating can be applied, dried/baked, etc., without losing its integrity or cracking. The animal food is best in the form of pieces or the like, such as, kibbles, biscuits, snacks, etc. The animal food pieces can be made by any suitable forming means, such as, extruding, molding, stamping, etc. The invention composition is used to reduce and control tartar accumulation on canine teeth.

The coating containing at least one inorganic pyrophosphate salt can be applied to animal foods having soft centers which may or may not contain at least one inorganic pyrophosphate. The total amount of inorganic pyrophosphate can be distributed between the coating and the soft center.

The coating can also be composed of SEALGUM and at least one inorganic pyrophosphate. SEALGUM is a trademark of Colloids Naturels Inc. of Bridgewater, New Jersey 08807 for a coating material which provides a gummed, shiny coating. The coating, for example, can be applied in the form of a solution, slurry or emulsion by using a rotative coating machine or using spray nozzles.

The animal food can be the dog food disclosed in commonly-owned, copending U.S. application Ser. No. 242,292, filed on Sept. 9, 1988, entitled "Chewy Dog Snacks", the pertinent parts of which are incorporated herein by reference. A chewy, semi-plastic, non-extruded, non-porous, microbiologically-stable dog food which includes: 12 to about 30 weight percent, based upon the total weight of the dog food, of gelatin; at least one acidulant; at least one cereal starch-containing textural agent; at least one release agent; at least one taste agent; at least one sugar; salt; and added water. The dog food is in a molded form. The dog food has a pH of about 3 to 5, and has a moisture content of about 10 to 25 weight percent, based upon the weight of the dog food. The process for preparing the dog food includes (a) mixing the dry components and liquid components with low speed agitation and continuing the mixing until a dough is obtained; (b) forming the dough by molding or rotary molding into molded snacks or biscuits; (c) conditioning the molded dough at 185° to 200° F. for about 7 to 8 minutes; and (d) packaging the molded dog snacks or biscuits in a protective package.

The coating and dog biscuits can be those of U.S. Pat. No. 4,822,626, and copending commonly-owned U.S. application Ser. No. 304,625, filed on Feb. 3, 1989, the pertinent parts of each are incorporated herein by reference. The biscuits with a baked-on proteinaceous coating, are produced comprising steps of:

- preparing a dough piece from a dough comprising flour, meal, fat and water;
- enrobing the dough piece with a viscous coating formulation comprising 10 to 30 weight percent of a dextrin carrier, 10 to 50 weight percent of meat, 10 to 30 weight percent of a glazing agent, 1 to 5 weight percent of polysaccharide gum, 5 to 15 weight percent of monosaccharide sugar, 5 to 15 weight percent of a disaccharide sugar, and water, all based upon total dry solids; and
- baking the dough piece to form a dry biscuit with a baked-on coating. The glazing agent can comprise a gelatin or a modified food starch, and the polysaccharide gum can be a xanthan gum.

The coatings are modified by the inclusion of at least one inorganic pyrophosphate.

The invention also involves swab, gauze and other like materials having adsorbed/adsorbed thereon a (aqueous) solution containing at least one inorganic pyrophosphate. The above information regarding amounts, types, preferred, etc., of the inorganic pyrophosphates also apply here. The disclosure herein concerning pyrophosphate solutions (aqueous, water/ethanol, ethanol, etc.) is applicable here. The solution preferably contains a thickener, preferably a humectant, such as, corn syrup, sugar and polyalcohols, such as, propylene glycol (preferred), sorbitol and glycerin.

Swabs are small sticks having a wad of an absorbent material, preferably cotton, usually wound around one end thereof. Gauze is a loosely woven cotton (or other suitable absorbent material) surgical dressing. The gauze can have a water-proof backing.

The solution (preferably aqueous) containing can be applied to the swab, gauze and like materials by any suitable means. Preferably the sorbent or tip portion of the swabs containing the cotton or like material is dipped into the solution which is usually heated at 45° to 200° F., preferably at about 60° to about 190° F., and most preferably at about 180° F. The treated swab can be packaged in a liquid-tight container without drying.

The treated swab can also be dried, preferably in a forced-air oven at a temperature of 75° to 300° F. The gauze is preferably dipped in the solution or sprayed with the solution. The solutions are usually and preferably heated as above. The treated gauze can be packaged in a liquid-tight container or package without drying. The treated gauze can also be dried as above.

The undried or dried swabs, gauze or like material are package, individually or in plurality, in liquid-tight or air-tight containers.

The undried or dried swabs, gauze or like material can be used to control or reduce tartar accumulation on animal teeth, such as, dog teeth, by contacting such teeth on a periodic basis (preferably each day) with such dried, coated swabs, gauze or like material.

The invention further involves swabs, gauze and other like materials having thereon and/or therein a coating containing at least one inorganic pyrophosphate. The above information regarding amounts, types, preferred, etc., inorganic pyrophosphates also applies here. The coating can contain the same amounts and type of inorganic pyrophosphates as in the case of the soft center portion.

The coating preferably is the coating described above which contains a surfactant, such as, lecithin or modified lecithin, xanthan gum (or other suitable polysaccharide gum), a starch or modified food starch, hydrogenated vegetable oil and a carrier, such as, malto-dextrin, flavorant (optional) and colorant (optional), but not including the animal fat. The above disclosure regarding such coating also applies to this invention embodiment, as appropriate. A suitable humectant, preferably propylene glycol, can be used in the coating formulation.

The coating can be applied to the swab, gauze and like materials by any suitable means. Preferably the sorbent or tip portion of the swabs containing the cotton or like material is dipped into the liquefied coating composition, which is usually heated at 45° to 200° F., preferably at about 60° to about 190° F., and most preferably at about 180° F. The coating can then be dried, preferably in a forced-air oven at a temperature of 75° to 300° F. The gauze is preferably dipped in the liquefied coating composition or sprayed with the liquefied coating composition. The liquefied coating compositions are usually and preferably heated as above and the drying is preferably done as above.

The dried, coated swabs, gauze or like material are package, individually or in plurality, in air-tight containers.

The dried, coated swabs, gauze or like material can be used to control or reduce tartar accumulation on animal teeth, such as, dog teeth, by contacting such teeth on a periodic basis (preferably each day) with such dried, coated swabs, gauze or like material.

The invention involves meat jerky, such as, beef jerky, having adsorbed/adsorbed thereon and/or thereon a (dried or undried) solution containing a (aqueous) solution containing at least one inorganic pyrophosphate. The above information regarding amounts, types, preferred, etc., of the inorganic pyrophosphates also applies here. The solution should use an aqueous, water/ethanol or ethanol solvent. As used in this entire document, a solution can include a slurry, suspension or the like where appropriate, for example, if a water-insoluble pyrophosphate is used.

The solution can be applied to the meat jerky by any suitable means. The meat jerky, particularly beef jerky,

is somewhat porous in structure. The solution is preferably applied by dipping the meat jerky in the solution, which is usually at 45° to 200° F., preferably at about 60° to about 190° F. and most preferably at about 180° F., or by spraying the solution onto the meat jerky (the solution temperatures being the same as above). The treated meat jerky can be dried by any suitable means, preferably in a forced-air oven at a temperature of 75° to 300° F.

The meat jerky can be packaged in air-tight containers.

Any meat jerky can be used. Naturally prepared jerky, also known as charqui, typically made with strips of striate muscle meat. Beef jerky products for canine consumption are usually prepared by the loaf extrusion method, the single strip extrusion method and the ribbon strip extrusion method. Coextensively aligned jerky are described in copending, commonly-owned U.S. application Ser. No. 164,418, filed on Mar. 4, 1988, and U.S. application Ser. No. 024,709, filed on Mar. 10, 1987, the pertinent portions of which are incorporated herein by reference.

The meat jerky can be used to prevent or reduce tartar accumulation on animal teeth, such as, dog teeth, by having the animal consume the treated meat jerky on a periodical (e.g., daily) basis.

The invention involves meat jerky, such as, beef jerky, having thereon and/or therein a coating containing at least one inorganic pyrophosphate. The above information regarding the amounts, types, preferred, etc., of inorganic pyrophosphates applies here.

The coating preferably is the coating described above which contains a surfactant, such as, lecithin or modified lecithin, xanthan gum (or other suitable polysaccharide gum), a starch or modified food starch, hydrogenated vegetable oil, a carrier, such as, malto-dextrin, animal fat, flavorant, colorant and water. The above disclosure regarding such coating also applied to this invention embodiment, as appropriate. A suitable humectant, preferably propylene glycol, can be used in the coating formulation.

The coating can be applied to the meat jerky gauze and like materials by any suitable means. Preferably the meat jerky is dipped into or sprayed with the liquefied coating composition, which is usually heated at 45° to 200° F., preferably at about 60° to about 190° F., and most preferably at about 180° F. The coating can then be dried, preferably in a forced-air oven at a temperature of 75° to 300° F.

The dried, coated meat jerky is packaged in air-tight containers.

The dried, coated, meat jerky can be used to reduce or reduce tartar accumulation on animal teeth, such as, dog teeth, by having the animal consume the treated meat jerky on a periodical (e.g., daily) basis.

The invention also includes the application of a solution containing at least one inorganic pyrophosphate

onto an animal food, such as, dog biscuits, semi-moist dog food, kibbles, extruded dog snacks and food, coated dog biscuits, etc. The above information regarding amounts, types, etc., of the inorganic pyrophosphate also applies here. Preferably the edible solvent used in the solution is water.

The solution is preferably applied to the animal food by means of a spray device, e.g., a spray bottle or a spray can. The treated animal food is used to reduce or prevent tartar accumulation on the animal's teeth, for example, dog teeth or cat teeth, by having the animal consume such treated animal food on a periodic (e.g., daily) basis.

DEFINITIONS

SAPP is sodium acid pyrophosphate.

TSPP is tetrasodium pyrophosphate.

TKPP is tetrapotassium pyrophosphate.

What is claimed is:

1. Baked dog food comprising a soft center portion and an outer portion, the center portion comprising at least one alkali metal inorganic pyrophosphate, the center portion being softer than the outer portion, the center portion containing about 0.1 to about 10 weight percent of said at least one alkali metal inorganic pyrophosphate, based upon the total weight of the baked dog food, said at least one alkali metal inorganic pyrophosphate being water soluble, the baked dog food being slightly acidic to neutral, the baked dog food having a water activity of 0.70 or less, and the baked dog food containing 15 weight percent or less, based upon the total weight of the baked dog food, of water.

2. The baked dog food as claimed in claim 1 wherein said at least one alkali metal inorganic pyrophosphate is a combination of trisodium monoacid pyrophosphate and tetrapotassium pyrophosphate, the soft center portion is composed of a soft dog biscuit dough and said at least one alkali metal inorganic pyrophosphate, and the soft dog biscuit dough contains a humectant.

3. The baked dog food as claimed in claim 1 wherein said at least one alkali metal inorganic pyrophosphate is a combination of sodium monoacid pyrophosphate and tetrapotassium pyrophosphate.

4. Meat jerky comprising meat jerky containing at least one alkali metal inorganic pyrophosphate, the amount of said at least one alkali metal inorganic pyrophosphate being sufficient to deliver from about 0.1 to about 5 weight percent, based on the total weight of the meat jerky containing at least one alkali metal inorganic pyrophosphate, of P_2O_7 , said at least one alkali metal inorganic pyrophosphate being water soluble, and said meat jerky being slightly acidic to neutral.

5. The meat jerky as claimed in claim 4 wherein said at least one alkali metal inorganic pyrophosphate is a combination of trisodium monoacid pyrophosphate and tetrapotassium pyrophosphate.

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EXHIBIT H

United States Patent [19]

Simone et al.

US005407661A

[11] Patent Number: 5,407,661

[45] Date of Patent: * Apr. 18, 1995

[54] **PET CHEW PRODUCT HAVING ORAL CARE PROPERTIES**

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subsequent to Mar. 22, 2011 has been
disclaimed.

[21] Appl. No.: 118,369

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Related U.S. Application Data

[63] Continuation of Ser. No. 822,241, Jan. 17, 1992, Pat.
No. 5,296,209.

[51] Int. Cl.⁶ 426 807; 426 805;
A61K 7/16; A61K 9/20; A61K 31/715; A61K
7/26

[52] U.S. Cl. 424/49; 424/401;
424/439; 424/442; 424/57; 426/807; 426/805

[58] Field of Search 424/49-58,
424/401, 439, 442, 447; 426/807, 805, 658, 648,
635, 630, 623, 618, 578, 560, 549, 3

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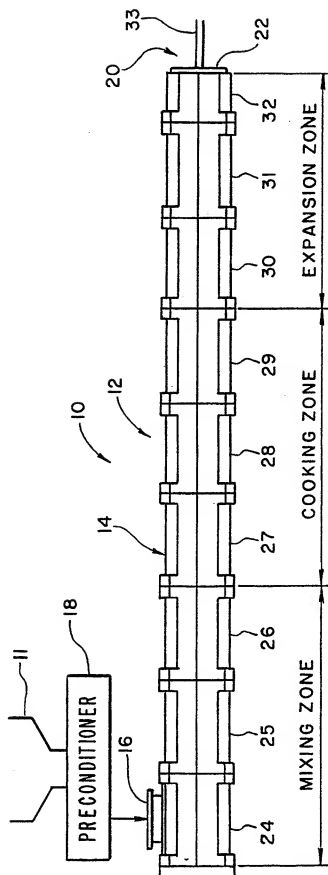
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ABSTRACT

An edible pet chew product having a flexible cellular matrix in which is contained a cellulosic fibrous material such as corn cob fractions having a mechanical cleansing function, which when chewed by the pet, effects a reduction in plaque, stain and tartar on the pet's teeth. An oral care additive may be incorporated in the matrix to inhibit dental problems, the composition of the cellular matrix being substantially inert to the oral care additive.

32 Claims, 1 Drawing Sheet

FIG. 1



PET CHEW PRODUCT HAVING ORAL CARE PROPERTIES

This is a Continuation of application Ser. No. 07/822,241, filed Jan. 17, 1992, now U.S. Pat. No. 5,296,209.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to an edible animal chew product having a flexible, inert cellular matrix containing a cellulosic fibrous material. The edible product, when chewed by animals such as dogs and cats, reduces plaque, stain and tartar.

DESCRIPTION OF THE PRIOR ART

Animal pets, such as dogs and cats, like their human counterparts, are subject to dental health problems. These problems can be traced to the formation of bacterial plaque which forms on the exterior surface of teeth. Plaque is an invisible, sticky film of bacteria, salivary proteins and polysaccharides which is not easily washed away. Plaque is now generally recognized as the main culprit of poor oral health. Bacteria that produce the acid for the caries process are held to the tooth surface by the plaque matrix as well as other bacteria which cause redness and swelling (gingivitis). The presence of these bacteria, if left untreated, may spread to cause malodor, periodontal disease, gingival pockets and bone loss.

Dental calculus, or tartar, is the result of the thickening and hardening (mineralization) of dental plaque. Tartar which is not easily removed accumulates on the tooth surface, mainly at the gingival margin opposite the salivary glands. It is a hard mineral deposit containing predominantly calcium and phosphate, very tightly bound to the tooth surface. Once it is formed, tartar is virtually impossible to remove except by a dental professional. Tartar can become unsightly if growth is left unimpeded, and elimination is desirable as the porous surface of the calculus will be covered by a thin layer of unmineralized plaque which can cause constant irritation of the gums and can trigger other problems once calculus is formed below the gum line.

Commercial animal pet foods do not provide sufficient surface cleaning to teeth to provide for plaque removal from the animal's teeth necessary for optimum dental health.

A variety of products are manufactured to provide animal pets with objects to chew or gnaw. They are intended to provide the pet with exercise for the teeth to maintain a healthy condition satisfying a need which arose when the natural pet food, raw meat, was replaced with processed pet foods. Rawhide strips knotted on the ends to resemble bones, for example, provide abrasion for cleaning teeth by removing tartar and massaging the gums, which is not provided by the typical canine dog food. The rawhide dog chews are expensive, and the indigestible leather fragments swallowed by the dogs frequently cause severe gastrointestinal blockage or diarrhea.

European patent 272,968 discloses a chewable product for dogs and other domestic animals wherein certain aqueous solutions of oral care agents, e.g., sodium fluoride (anti-caries agent), sodium benzoate (anticalculus agent) and bromochlorophene (antimicrobial/anti-plaque agent) are used to soak rawhide, beef tendon, or

ligament. The solution treated product is then dried whereby the oral care agents are absorbed into the surface of the product.

U.S. Pat. Nos. 5,000,940 and 5,000,943 disclose baked dog biscuits containing an inorganic pyrophosphate salt, e.g., tetrasodium pyrophosphate, which when chewed and/or eaten by dogs cause a reduction in tartar accumulations on their teeth.

The oral care agents incorporated in the pet food products of the prior art have either limited efficacy in oral care, or are incompatible and deactivated by the ingredients found in the products into which these agents are incorporated. For example, anti-tartar pyrophosphate salts incorporated in pet food products containing an excess of polyvalent cations, and particularly calcium, are rendered inactive by the calcium ion interacting with the pyrophosphate rendering it insoluble and thereby inactive.

Attempts to incorporate other oral care agents such as fluoride compounds in animal chews were unsuccessful as these compounds were also incompatible and unstable with ingredients from which the pet food product was fabricated.

A further disadvantage of the prior art pet oral care products is that they are baked products which are hard and brittle and, although abrasive and initially effective to remove plaque from teeth, quickly lose their effectiveness when chewed because rapid fracture of the product leads to loss of contact of the product with the teeth.

There is therefore a need in the pet food field for a product which is edible and consumable without gastrointestinal complications and effective to remove plaque and to inhibit the formation of tartar in pet animals such as dogs and cats.

SUMMARY OF THE INVENTION

This invention is directed to an edible animal chew product having a flexible cellular matrix in which is incorporated a cellulosic fibrous material having a mechanical cleansing function which, when chewed by the animal, reduces tartar, stain and plaque on the animal's teeth through a physical cleansing action without causing gastrointestinal distress. An oral care agent may be incorporated in the matrix to inhibit dental health problems. When chewed, the flexible, cellular product does not easily fracture and the drag created as the product is chewed by the animal increases the time that the product is retained in the animal's mouth cavity and in contact with its teeth. The product is extruded from ingredients which are inert to oral care additives to assure maximum bioavailability of the additives. The extruded product preferably contains starch, cellulosic fibers, humectant, proteinaceous binder and one or more oral care additives.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In general, the edible chew product of the present invention is made by admixing a starch containing ingredient, a cellulosic fibrous material, humectant, and proteinaceous binder and oral care additives such as tartar control and anticaries additives and then subjecting the moistened admixture to mechanical working in an extruder at an elevated temperature so as to extrude an expanded product having a flexible, cellular matrix.

In the preparation of the chew product of the present invention, the solid components of the chew product;

namely cellulosic fibrous material, starch, and proteinous binder together with any oral care additive, are first admixed together.

The cellulosic fibrous component which provides mechanical cleansing ability to remove dental plaque, stain, tartar and other materia alba accumulating on the animal's tooth surfaces when the product is chewed by the animal is a cellulosic fibrous material including corn cob fractions, cellulose fiber and other plant fibers or microbial polysaccharides. Corn cob fractions are preferred.

Although the cellulosic fibrous materials are not digested by the pet, the pet's digestive system is capable of handling such fibers by passing them through its system substantially unchanged. In fact, the cellulosic fibrous materials provide increased roughage and bulk so as to assist the pet in the digestion of food.

Generally, cellulosic fibrous materials such as corn cob fractions are included in the chew product at a concentration of about 20 to about 50% by dry weight of the chew product and preferably about 25 to about 35% by weight. Corn cob fractions generally range in particle size from about 5 to about 1000 microns and preferably about 20 to about 250 microns.

Corn cob residues from both the woody and shaft portions of the cob are compatible with oral care additives such as tartar control additives including inorganic alkali pyrophosphate salts which are incorporated in the chew product. Corn cob fractions serve the additional function of being moisture absorbent contributing resiliency and flexibility to the chew product. Further, the corn cob fractions also provide a greater range of earth tones and contribute a positive aroma to the chew product.

The term "starch" as used herein includes within its meaning amylose, amylopectin, amylose containing mono-, di-, tri- and polysaccharides and mixtures thereof such as those derived from wheat, corn or like cereals or tubers. Starch forms a matrix superstructure into which the oral care additives including cellulosic fibrous particles and oral care additives are suspended.

During the fabrication of the chew product by mechanical working in an extruder, starch materials function as an expansion medium. The gelatinization of the mechanically worked product mass due to the heat and moisture introduced during the extrusion process swells the starch granules releasing amylose and amylopectins to thicken and form a gelatinized matrix. The proteinous binder undergoes a similar gelatinization reaction whereby the starch and binder join to form the cellular matrix structure.

Suitable starch materials useful in the preparation of the chew product of the present invention include wheat starch, corn starch, oat starch, rice starch and other complex carbohydrates. The starch is included in the chew product at a concentration of about 30 to about 60% by dry weight and preferably about 40 to about 55% by dry weight of the product.

The proteinous binder incorporated in the chew product has an adhesive effect and binds together the solid particles to form a cohesive, integral mass when the ingredients are heated and extruded to form the expanded cellular product.

Proteinous binder materials suitable for use in the preparation of the chew products of the present invention include collagen and gelatin. Collagen derived from the digestion of beef bones is preferred in the practice of the invention. Gelatin derived from both

pork skin and animal bones is also a preferred binder material. The binder material is used in the preparation of the chew product of the present invention at a concentration of about 5 to about 20% by weight of the chew product and preferably about 8 to about 10% by weight. Collagen and gelatin materials also contribute to the flexible texture of the extruded cellular matrix chew product.

Oral care additives that may be incorporated in the chew products of the present invention include tartar control additives such as inorganic pyrophosphate salts including dialkali or tetra-alkali metal pyrophosphate salts such as $\text{Na}_4\text{P}_2\text{O}_7$, $\text{K}_4\text{P}_2\text{O}_7$, $\text{Na}_2\text{K}_2\text{P}_2\text{O}_7$, $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$, and $\text{K}_2\text{H}_2\text{P}_2\text{O}_7$ and combinations thereof. The tartar control additives are incorporated in the chew products of the present invention at a concentration effective to inhibit tartar formation on the animal's teeth. Suitable concentrations of the pyrophosphate salts range from about 0.5 to about 15% by dry weight and preferably 1.0 to about 10% by dry weight of the chew product.

It is further preferred that a combination of alkali metal pyrophosphate salts be used and particularly a combination of potassium and sodium pyrophosphates at a weight ratio of about 5:1 to 1:1. A weight ratio of about 3:1 is especially preferred.

In addition to pyrophosphate tartar control additives, fluoride containing salts may also be incorporated in the chew product to inhibit phosphate enzymes that hydrolyze and degrade the pyrophosphate salts whereby the tartar control efficacy of these salts is otherwise reduced.

The fluoride-providing salts used in the practice of the present invention are characterized by their ability to release fluoride ions in water and by substantial freedom from reaction with the other ingredients of the chew product. Among these materials are inorganic salts, for example, sodium fluoride, potassium fluoride, a tin fluoride such as stannous fluoride or stannous chlorofluoride, and sodium monofluorophosphate. Alkali metal and tin fluorides, such as sodium fluoride, stannous fluoride, sodium monofluorophosphate and mixtures thereof, are preferred.

When included in the chew product, any suitable minimum amount of the fluoride salt may be used, but it is preferable to employ sufficient salt to release from about 0.05% to 1%, and preferably about 0.1% of fluoride ion. Typically, in the cases of alkali metal fluorides and stannous fluoride, the salt is present in an amount up to 2% by weight, based on the weight of the product, and preferably in the range of from 0.05% to 0.5% by weight.

Other agents suitable for incorporation in the chew product of the present invention include synthetic anionic linear polymeric polycarboxylates which are employed in the form of their partially or preferably fully neutralized water soluble alkali metal (e.g. potassium and preferably sodium) or ammonium salts. The polycarboxylates, like the fluoride salts, inhibit salivary enzymes which hydrolyze pyrophosphates to an inactive form. Preferred are 1:4 to 4:1 copolymers of maleic anhydride or acid and a polymerizable ethylenically unsaturated monomer, preferably a lower alkyl vinyl ether such as methoxyethylene, having a molecular weight of about 30,000 to about 1,000,000. These copolymers are available commercially from GAF Corporation under the trademark Gantrez, e.g. Gantrez S-97 Pharmaceutical Grade (molecular weight 70,000). The

polycarboxylates are incorporated in the chew product of the present invention at a concentration of about 0.25 to about 4% by weight and preferably about 1.0 to about 3.0% by weight.

To impart flexibility to the chew product, it is advantageous to adjust the moisture content of the chew product so that the final product contains water at a concentration equal to or greater than 12% by weight and preferably 16 to 35% by weight.

A humectant is incorporated in the chew product to enhance the flexible chew texture and retain moisture so as to maintain the texture when the chew is stored at ambient temperatures. The preferred humectants are glycerine and sorbitol. Typically, the humectant is incorporated in the chew product at a concentration of about 1 to 15% by weight and preferably about 4 to about 10% by weight of the product.

Suitable flavoring materials may be employed to enhance the palatability of the chew product of the present invention. Examples of suitable flavoring constituents include garlic, wood smoke, meat, and fish extracts and fermentation residues, suitably, the flavoring agent comprises from about 0.01 to 5 percent by weight or more of the chew product of the present invention and preferably, about 0.8 to about 1.5 percent by weight.

The extruded chew product of the present invention is a solid composition having a cellular matrix and a chewy non-brittle texture which is not readily fractured when chewed by the animal and hence offers the animal the intended teeth cleansing benefits stemming from the mechanical cleansing and other contacts with the cellulosic fibrous particles and contained in the chew product. In addition, as the product does not fracture as the animal gnaws on the product, the product remains in contact with the teeth prolonging the bioavailability of the oral care additives contained therein.

As all the ingredients of the chew product are substantially inert and non-reactive with the oral care additives, they are compatible with the oral care additives so that these additives are stable and retain their efficacy during storage before use.

Due to the presence of relatively high moisture levels in the chew product, preservatives such as sodium benzoate, potassium sorbate, sodium propionate, sorbic acid, or paraaminobenzoic acid esters (parabens) alone and in combination may be incorporated into the product to inhibit mold bacteria, yeast formation and growth. The preservative may be incorporated in the chew product at a concentration in the range of about 0.05 to about 4.0% by dry weight and preferably in the range of about 0.1 to about 0.6% by dry weight.

To prepare the chew product, the starch, humectant, proteinaceous binder, cellulosic fibrous material and oral care additives are transferred to a steam pre-conditioner and subjected to steam and moisture in order to adjust the moisture content to between about 20 and 50% by weight. The conditioned mixture is then extruded under conditions of elevated temperature and pressure to form a continuous ribbon of expanded cellular product that is segmented into discrete particles or pieces by a rotating knife or other cutting means upon exit of the ribbon from the extruder. The chew particles are then allowed to cool and dry at a controlled temperature, e.g. 65-75° F., to adjust the moisture level to about 10 to about 30% by weight.

BRIEF DESCRIPTION OF THE DRAWINGS

In the figure, there is shown one embodiment of an extrusion apparatus 10 which can be used to manufacture the cellular chew product. The extrusion apparatus 10 includes an extruder 12 having a barrel 14 with an inlet 16 located below the outlet of a preconditioner 18; the extruder 12 also having an outlet 20 with a die 22. Hopper 11 is provided to pre-mix the ingredients prior to preconditioning. The barrel 14 as depicted comprises nine barrel sections 24, 25, 26, 27, 28, 29, 30, 31, 32, although the number of barrels may vary without departing from the principles of the present invention. The barrel sections are interconnected to present an elongated bore through the barrel 14 of the extruder 12. Two co-rotating, flighted material advancing screws (not shown) are received in the bore of the barrel and are intermeshed along the majority of the length of the extruder barrel 14 and terminate in the die section 22. The screws feed material to and through the extruder assembly, including a die, at an appropriate flow rate and under appropriate flow conditions. Extrusion apparatus 10 of the type illustrated in the figure is manufactured by Wenger Manufacturing such as the Wegner TX-52 (research extruder) or Wenger TX 80 twin screw (commercial extruder). The pre-conditioner 18 shown in the figure is also manufactured by Wenger Manufacturing, Inc.

In preparing the extruded cellular product of the present invention, using the Wenger TX-80, the solid ingredients from which the chew product is extruded are first pre-mixed in a mixer such as a ribbon mixer and fed to hopper 11. These pre-mixed ingredients include a cellulosic fibrous material such as corn cob fractions, starch, oral care additive, preservative and binder. The pre-mixed solid ingredient is then fed to the preconditioner 18 and admixed with the humectant and other liquid ingredients which are fed directly into the preconditioner 18. In the preconditioner 18 the mixture of ingredients is fed thereto at a rate between 10 and 20 pounds (lbs.)/minute and is further mixed with water which is introduced into the preconditioner at a rate of 0.5 to 4.0 lbs./minute. The temperature of the mixture is raised from ambient to 150° to 200° F. (170° F. being preferred) by the injection of steam into the preconditioner 18 at the rate of 0.5 to 5.0 lbs./minute. Total residence time in the preconditioner 18 generally ranges from 0.5 to 1.5 minutes.

Preconditioning the mixture with steam and water initiates hydration of the binder which is completed by the mechanical working during the extrusion process. The humectant is desirably added after the mixture has been first contacted with the steam/water treatment so as not to compete with the binder for the moisturizing treatment in the preconditioner.

Once the mixture of ingredients and water is introduced into the extruder barrel 14, the mixture is advanced along the length of the barrel 14 by axial rotation of the twin screws. The mixture is sequentially advanced through the extruder and finally through the die 22 at the outlet of the extruder 12, the die 22 having an orifice shaped to yield a ribbon of expanded cellular product. As the mixture passes through the barrel sections 24, 25, 26, 27, 28, 29, 30, 31, and 32, it is mixed, cooked at product temperatures in the range of 200°-280° F. to cause expansion of the extrudate product as it leaves the die 22.

Typically, barrel sections 24, 25 and 26 comprise a Mixing Zone where the moisturized product mixture is introduced and compressed into the extruder barrel 14 at a temperature of 100°-120° F., followed by a Cooking Zone, barrel sections 27, 28 and 29 where the mixture is cooked at a temperature of about 140° to about 200° F. This is followed by an Expansion Zone (barrel sections 30, 31, 32) where the gelatinized mixture undergoes expansion. Thereafter, the product further expands as it is blown out through the orifice of the die 22 as ribbon 33. The blowing out induces the product to further puff or expand to form the desired cellular matrix product.

The pressure within the extruder ranges from about 0 to 100 psi in the Mixing Zone, about 10 to 200 psi in the Cooking Zone and about 100 to 1,000 psi in the Expansion Zone. The residence time in any one zone is about 10 to about 45 seconds and generally about 30 seconds.

The expanded cellular product as it leaves the extruder has a moisture content of about 10 to about 35% water by weight and preferably about 15 to about 25% water by weight.

The thickness of the extruded cellular product is controlled so that it has a thickness of about 0.25 to about 0.75 inches upon leaving the extruder die 22. The ribbon of cellular matrix extrudate 33 is then cut and subdivided into longitudinal 1 to 5 inch sections and allowed to cool and dry to a moisture content of about 12 to about 35% by weight water.

The invention is further illustrated by the following specific but non-limiting Example.

EXAMPLE

A mix for the preparation of a dog chew designated "Chew Product I" was prepared which contained the following ingredients:

Ingredient	Weight %
Wheat Starch	45.42
Corn Cob Fraction*	32.58
Gelatin (225 Bloom)	9.87
Glycerin	4.44
Potassium Sorbate	0.30
Gantrez S-97 (approx. 13% soln)	1.92
K ₂ P ₂ O ₇	4.00
Na ₂ P ₂ O ₇	1.38

*60 mesh fraction. Particle size less than 0.15 millimeter, 90% less than 150 microns. Typical sieve analysis as follows:

mesh	%	mm
>50	0.1	0.30
<50 > 60	2.0	0.25
<60 > 100	55.0	0.15
<100	45.0	<0.15

The wheat starch, corn cob fraction, pyrophosphate salts, and potassium sorbate were fed to the hopper 11, of a Wenger research twin screw extruder (Model No. TX-52) equipped with a preconditioner 18, and processed to obtain an expanded chew product having a flexible cellular matrix. The TX-52 machine was of the type schematically illustrated in the figure and was provided with two rotatable, flighted material advancing screws and had a total of 9 barrel sections and terminated in a rounded rectangular port with rate controlling throttle valve.

This mixture having a moisture content of 10.82% was fed to the preconditioner at a rate of 150.0 pounds per hour. The mixture was raised in temperature to 170° F. by the injection of steam introduced at a rate of 0.070 pounds per minute into the preconditioner. Water was

introduced into the preconditioner at the rate of 0.50 pound per minute. The glycerin and Gantrez ingredients were added to the preconditioner at this point.

Next, the mixture was fed into the inlet 16 of the extruder mixing zone and steam was introduced into the mixture at a rate of 0.080 pounds per minute. The screws of the extruder were rotated at a speed of 380 rpm.

Temperatures of the barrel sections were maintained at 111° F., 111° F., 149° F., 193° F., 182° F., 151° F. and 212° F. for the second, third, fourth, fifth, sixth, seventh, eighth and ninth barrel sections respectively. Product rate through the extruder was about 200 pounds per hour. The product was extruded as continuous flexible ribbon 1.0 inch wide and 0.25 inch thick having a cellular matrix with a water content of 28.01% by weight. The extrudate ribbon was cut into 1.5 foot sections at the extruder head with a rotating knife. The extrudate sections were allowed to dry at ambient temperature in air for one hour. The air dried extrudate sections were determined to have a moisture content of 20% by weight. The dried extrudate sections were further subdivided into 2.75 inch pieces to prepare the final chew product. The final chew product had a spongy, flexible cellular matrix, light tan in color.

A group of 10 pure-bred beagle dogs (ages 1 to 6 years) were individually fed 4 pieces of the chew product daily together with a diet of a commercial canned dog food sold under the name "Hills Canned Canine Maintenance" by Hills Pet Products, Topeka, Kansas, adequate to maintain the weight of each dog for a one week test period. The dogs were fed the canned dog food at about 8 a.m. and two (2) chews at about 10 a.m. and again at about 3 p.m. The individual piece of chew product each weighed about 5 grams.

In observing the eating style of the dogs, it was noted that although the canned dog food ration tended to be gulped by the dogs, the spongy cellular chew product was chewed repeatedly before being swallowed. This chewing action increased the residence time that the chew product was in the dog's mouth thereby increasing the contact time with the teeth of the corn cob particles and pyrophosphate salts contained in the product.

Prior to the feeding test, each dog had been given a thorough dental prophylaxis to remove existing soft and hard deposits on the buccal surfaces of the maxilla and mandible (a total of 22 teeth per dog).

The teeth of each dog in the group was examined for plaque, stain and tartar upon the completion of the test period.

In this examination, each tooth was divided horizontally into a gingival half (next to the gumline) and an occlusal half (away from the gumline). Plaque was scored visually on the corresponding tooth surfaces after staining with 3% erythrosin solution using the following criteria: 1, plaque coverage of up to 25% of the buccal tooth surface; 2, plaque covering between 25 and 50% of the buccal tooth surface; 3, plaque covering between 50 and 75% of the buccal tooth surface and 4, plaque covering between 75 and 100% of the buccal tooth surface.

The thickness of the plaque was scored as follows: Light=1, Medium=2 and Heavy=3. Coverage and thickness scores for each individual tooth surface were then multiplied, to give a total score for that tooth surface. Gingival and occlusal scores were added for each tooth. All tooth scores were added for each animal,

then divided by the number of teeth scored to give a mean plaque score for the animal. A mean group plaque score was obtained by averaging individual scores of all animals in the group.

Stain was scored visually on the corresponding tooth surfaces after drying the tooth surface with a gentle jet of air using the following criteria; each tooth was divided vertically into 3 segments, mesial, buccal and distal; the coverage and color of the stain in each segment was then graded independently; 1, stain coverage of up to 25% of the (mesial, buccal or distal) surface, 2, up to 50%; 3, up to 75% and 4, up to 100%. The stain color was scored 1,L (light), 2,M (medium) and 3,D (dark). Coverage and thickness scores for each individual tooth surface were then multiplied, to give a total score for that tooth surface. Mesial, buccal and distal segment scores were added for each tooth. All tooth scores were added for each animal, then divided by the number of teeth scored to give a mean stain score for the animal. A mean group stain score was obtained by averaging individual scores of all animals in the group.

Tartar was scored visually for area coverage on the corresponding tooth surfaces in the same manner as stain.

The plaque, stain and tartar scores for this group of dogs which were fed Chew Product I are recorded in Table I below. For purposes of comparison, the procedure of the Example was repeated with the exception that the dogs were not fed the chew product. The results of this test are also recorded in Table I below with the designation "Control".

The procedure of the Example was repeated with the exception that the chew product fed to the dogs was derived from an extrudate which did not contain any pyrophosphate salts. This chew product was designated "Chew Product II". The plaque, stain and tartar scores for the group of dogs fed Chew Product II are also recorded in Table I.

For purposes of further comparison, the procedure of the Example was repeated with the exception that, instead of the chew product of the present invention, the dogs were fed four biscuits of a commercially available baked biscuit product containing a pyrophosphate salt oral care additive. The results of this test are also recorded in Table I below with the designation "Comparison I".

TABLE I

Chew Product	Mean Group	Mean	Mean Group
	Plaque Score	Stain Score	Tartar Score
CHEW PRODUCT I	5.59	1.26	2.43
CHEW PRODUCT II	6.77	2.35	3.49
COMPARISON I	8.34	3.24	4.54
CONTROL	8.87	3.60	5.10

The above results show that the chew product of the present invention, namely Chew Products I and II, is significantly effective in reducing plaque, stain and tartar in dogs, especially when compared to the control as well as the comparative chew product.

Based on the mean group scores of Table I, the percent reduction obtained in plaque, stain and tartar as obtained with the chew products of the present invention (Chew Products I and II) or the commercial baked product compared to not feeding the dogs a chew product, is summarized in Table II below.

TABLE II

	% REDUCTION		
	PLAQUE	STAIN	TARTAR
CHEW PRODUCT I	37.0	65.0	52.4
CHEW PRODUCT II	23.7	34.7	31.6
COMPARISON I	6.0	10.0	11.0

The data recorded in Table II demonstrate the significantly greater reduction in plaque, stain and tartar obtained with the chew product of the present invention when compared to a commercial baked product containing a pyrophosphate salt oral care additive.

What is claimed is:

1. A composition to be chewed by an animal for removing plaque, tartar and stain from the teeth of the animal, which composition comprises an edible, solid unbacked extrudate product having a chewable, flexible cellular matrix in which is incorporated an effective mechanical cleansing amount of a cellulosic fibrous material, water to adjust the moisture concentration equal to or greater than 12% by weight and a humectant at a concentration of about 1 to about 15% by weight, said moisture imparting flexibility to the composition and retaining moisture so as to maintain the texture when the composition is stored.

2. The composition of claim 1 in which an effective amount of a pyrophosphate salt tartar control oral care additive is incorporated in the cellular matrix, the cellular matrix being substantially inert to the oral care additive.

3. The composition of claim 1 wherein the cellular matrix is comprised of a starch.

4. The composition of claim 1 wherein the cellular matrix has incorporated therein a proteinaceous binder.

5. The composition of claim 2 wherein the oral care additive is an alkali metal pyrophosphate salt.

6. The composition of claim 5 wherein the alkali metal pyrophosphate salt is a mixture of potassium and sodium pyrophosphates at a weight ratio of about 5:1 to about 3:1.

7. The composition of claim 1 wherein water is contained in the cellular matrix at a concentration of about 10 to about 35% by weight.

8. The composition of claim 3 wherein the starch is incorporated in the cellular matrix at a concentration of about 30 to about 60% by weight.

9. The composition of claim 3 wherein the starch is wheat starch.

10. The composition of claim 4 wherein the proteinaceous binder is incorporated in the product at a concentration of about 5 to about 20% by weight.

11. The composition of claim 5 wherein the pyrophosphate salt is incorporated in the product at a concentration of about 0.5 to about 15% by weight.

12. The composition of claim 1 wherein a humectant is incorporated in the product at a concentration of about 1 to about 15% by weight.

13. The composition of claim 12 wherein the humectant is glycerin.

14. The composition of claim 2 wherein a synthetic anionic linear polymeric polycarboxylate is incorporated therein.

15. The composition of claim 14 wherein the polycarboxylate is a copolymer of maleic anhydride or acid and methoxyethylene.

16. The composition of claim 15 wherein the polycarboxylate is incorporated in the composition at a concentration of about 0.25 to about 4% by weight.

17. A method of removing plaque, tartar and stain from the teeth of an animal which comprises feeding the animal an edible, chewable, flexible unbaked extrudate product having a cellular matrix, the cellular matrix having incorporated therein of an effective mechanical cleansing amount of a cellulosic fibrous material, water to adjust the moisture concentration equal to or greater than 12% by weight and a humectant at a concentration of about 1 to about 15% by weight, said moisture imparting flexibility to the composition and retaining moisture so as to maintain the texture when the composition is stored and the animal chewing product.

18. The method of claim 17 wherein there is incorporated in the cellular matrix a pyrophosphate salt tartar control oral care additive, the ingredients forming the cellular matrix being substantially inert to the oral care agent.

19. The method of claim 17 wherein the cellular matrix is comprised of a starch.

20. The method of claim 17 wherein the cellular matrix contains a proteinaceous binder.

21. The method of claim 18 wherein the oral care additive is an alkali metal pyrophosphate salt.

22. The method of claim 21 wherein the alkali metal pyrophosphate salt is a mixture of potassium and so-

dium pyrophosphates at a weight ratio of about 5:1 to about 3:1.

23. The method of claim 17 wherein water is contained in the cellular matrix at a concentration of about 10 to about 35% by weight.

24. The method of claim 19 wherein the starch is incorporated in the cellular matrix at a concentration of about 30 to about 60% by weight.

25. The method of claim 19 wherein the starch is wheat starch.

26. The method of claim 20 wherein the proteinaceous binder is incorporated in the product at a concentration of about 5 to about 20% by weight.

27. The method of claim 21 wherein the pyrophosphate salt is incorporated in the product at a concentration of about 0.5 to about 15% by weight.

28. The method of claim 17 wherein a humectant is incorporated in the product at a concentration of about 1 to about 15% by weight.

29. The method of claim 28 wherein the humectant is glycerin.

30. The method of claim 17 wherein a synthetic anionic linear polymeric polycarboxylate is incorporated therein.

31. The method of claim 30 wherein the polycarboxylate is a copolymer of maleic anhydride or acid and methoxyethylene.

32. The method of claim 30 wherein the polycarboxylate is incorporated in the product at a concentration of about 0.25 to about 4% by weight.

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EXHIBIT I

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Cupp et al.
Appl. No.: 10/037,941
Conf. No.: 7917
Filed: January 3, 2002
Title: DENTAL DIET FOR REDUCING TARTAR
Art Unit: 1761
Examiner: K. Hendricks
Docket No.: 115808-330

SUPPLEMENTAL AFFIDAVIT UNDER 37 C.F.R. § 1.132

Sir:

I, Carolyn J. Cupp, hereby state as follows:

1. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein.
2. This Affidavit supplements the previously submitted Affidavit under 37 C.F.R. § 1.132 signed by me on January 26, 2006 (the "Affidavit") and submitted along with a response to the Patent Office on February 1, 2006, which is hereby incorporated by reference.
3. The present claims are directed to, in part, a dry pet food that will reduce tartar when chewed by the pet. It has been surprisingly found that an unstriated pet food in accordance with the present invention having a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³ increases the removal of plaque and tartar build-up.
4. As one having ordinary skill in the art, I believe that *Collings* fails to disclose or suggest a pet food product having a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³. Instead, I believe *Collings* is directed to an expanded pet food product having a low density texture.

Appl. No. 10/037,941

5. Approximate calculations to arrive at the density of the pet food product taught by *Collings* were performed based on information derived from Example 1 in *Collings* along with reasonable estimates by one skilled in the art of the type of product container and filling of the pet food not explicitly given by *Collings*. A copy of the calculations based on different the assumptions of the type of product container and filling of the pet food is attached hereto as Exhibit B.

6. Pet food density calculations were performed using several assumed values regarding the weight and thickness of the container holding the pet food in Example 1 in *Collings*. The assumed values for the containers were based on the typical pet food containers used to hold the category of pet food as taught by *Collings*. Accordingly, the dimensions of an applicable pet food package described by *Collings* having good stacking capabilities, recloseable lid and good barrier properties were used. Pet food density calculations were also performed using a reasonably assumed void space of 10% for the filled product in the container. As observed in Exhibit B, all of the calculations give *Collings'* pet food product a density at or below 12 lbs/ft³.

7. For the foregoing reasons, as one having ordinary skill in the art, I believe that *Collings* fails to disclose or suggest a pet food product having a density that ranges from about 16.8 lbs/ft³ to about 20 lbs/ft³.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: 8-1-06

Carolyn J. Cupp
Name: Carolyn J. Cupp

RELATED PROCEEDINGS APPENDIX

None.